AD_____

Award Number: DAMD17-98-1-8580

TITLE: Chemoprevention Trial of Selenium and Prostate Cancer

PRINCIPAL INVESTIGATOR: Larry Clark, Ph.D., MPH

CONTRACTING ORGANIZATION: University of Arizona
Tucson, Arizona 85716

REPORT DATE: October 1999

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	October 1999	Annual (1-Oct-98 - 30-Sep-99)

4. TITLE AND SUBTITLE
Chemoprevention Trial of Selenium and Prostate Cancer

5. FUNDING NUMBERS
DAMD17-98-1-8580

6. AUTHOR(S)
Larry Clark, Ph.D., MPH

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
University of Arizona
Tucson, Arizona 85716

E-MAIL:
lcclark@u.arizona.edu

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSORING / MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for public release; distribution unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT ***(Maximum 200 Words)***

The principal purpose of this trial is to assess the potential for the essential nutrient **selenium** (Se) to inhibit the progression of prostate cancer. The primary endpoints for this trial are the velocity at which the primary clinical marker of prostate cancer progresses, serum prostate-specific antigen (PSA) increases and the rate of development of metastases in the population undergoing prostatectomy. A key set of secondary end points consists of markers of tissue changes between initial diagnostic biopsy and radical prostatectomy. The scope of work is to randomize at least 110 participants to either a placebo or Se dosages of 200 μg, or 400 μg/day. Major findings have not yet occurred due to slow patient accrual. Recruitment was hindered in this trial by our decision to require frozen tissue specimens at both biopsy and radical prostatectomy. Based on the advice of our key consulting urologist, we have decided to work with both frozen tissue specimens and paraffin-embedded specimens; he and our collaborating investigators have informed us that the use of paraffin-embedded specimens will substantially increase our study accrual. We anticipate expedient results and significance as patient accrual accelerates.

14. SUBJECT TERMS
Prostate Cancer

15. NUMBER OF PAGES
197

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

NSN 7540-01-280-5500

Standard Form 298 (Rev. 2-89)
Prescribed by ANSI Std. Z39-18
298-102

FOREWORD

Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the U.S. Army.

___ Where copyrighted material is quoted, permission has been obtained to use such material.

___ Where material from documents designated for limited distribution is quoted, permission has been obtained to use the material.

___ Citations of commercial organizations and trade names in this report do not constitute an official Department of Army endorsement or approval of the products or services of these organizations.

N/A In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and use of Laboratory Animals of the Institute of Laboratory Resources, national Research Council (NIH Publication No. 86-23, Revised 1985).

X For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

N/A In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

N/A In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

N/A In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

10/29/99

PI - Signature **Date**

Table of Contents

INTRODUCTION

The principal purpose of this trial is to assess the potential for the essential nutrient **selenium** (Se) to inhibit the progression of prostate cancer. The rationale for this trial is based on the results of the Nutritional Prevention of Cancer (NPC) Trial, our double-blind, randomized clinical trial, which observed a 63% reduction in prostate cancer incidence during the initial 10 years of follow-up in participants receiving 200 μg of Se compared to those assigned to a placebo[1]. This trial will randomize participants to either a placebo or one of two Se dosages, 200 μg, or 400 μg/day. A study population of prostate cancer subjects was selected because they represent a population that may benefit from selenium's potential to prevent the morbidity and mortality associated with prostate cancer and prostate cancer treatment. The primary endpoints for this trial are the velocity at which the primary clinical marker of prostate cancer progression, serum prostate-specific antigen (PSA) increases and the rate of development of metastases in the population undergoing prostatectomy. A key set of secondary end points consists of markers of tissue changes between initial diagnostic biopsy and radical prostatectomy. Additional endpoints are time to disease progression, initiation of hormone therapy, and the time to documented metastatic disease. The trial will randomize at least 110 patients, in order to have an 80% power to detect a 70% decrease in the velocity of PSA with an alpha of 0.05 during an expected average follow up of 24 months in funding phase one and an additional 20 months in funding phase two of the trial. The minimum treatment effect of 70% was selected for this study of prostate cancer patients because it is similar to the treatment effect observed in the NPC trial among non-melanoma skin cancer patients. Recruitment was hindered in this trial by our decision to require frozen tissue specimens at both biopsy and radical prostatectomy. Based on the advice of our key consulting urologist, that this requirement was seriously limiting recruitment, we have decided to work with both frozen tissue specimens and paraffin-embedded specimens; he and our collaborating investigators have informed us that allowing collaborators to use paraffin-embedded specimens will substantially increase our study accrual. Unfortunately, Dr. Clark has encountered severe health problems and this has limited our ability to recruit collaborating urologists and deal with study problems. However, he recently enlisted Dr. James Marshall (CV enclosed), to assist with the conduct of this trial. Dr. Marshall has taken an increasingly active role; it was his decision to shift to the use of paraffin-embedded tissue.

BODY

Task 1: Training and Preparation for Trial

The clinical trial questionnaires that were used in Dr. Clark's *Nutritional Prevention of Cancer* (NPC) and *Watchful Waiting* (WW) trials were modified for this trial as appropriate (Appendix I). A Procedures Manual (Appendix II) has been written to incorporate the data entry protocols, and the coordinating staff has been trained to enter the data into the system. In addition, data entry programs and monitoring routines were written in Visual Basic and Microsoft Access to accommodate the data collection (Appendix III).

Cypress Systems (Fresno, CA) provided the Selenium and Baker's Yeast for the study supplements and Pharma Nord (Denmark) manufactured, tableted, and boxed the pills for this trial in dosages of 200 μg and 400 μg selenium, and a matched placebo. Blood sample

collection kits and processing supplies were acquired to enable us to assay the specimens. Dr. Clark prepared the necessary randomization codes.

Task 2: Subject Recruitment, Enrollment and Randomization

The recruitment rate for this study has been lower than expected by our original projections. This is partly because of new treatments for prostate cancer (such as "seeding"). In addition, the incidence of prostate cancer appears to have declined slightly: this is probably the result of the detection of large numbers of early stage cases as a result of the advent of the PSA test. The media saturation stemming from the publication of our results in JAMA (December 25, 1996) regarding a possible reduction in the incidence of prostate cancer due to selenium intake, may have led a large number of prostate cancer patients to take selenium, which then makes them ineligible. Summarized below are reasons for the lower recruitment rates, and solutions to increase the recruitment rate:

Reasons for lower-than-expected recruitment rate:

1) More prostate cancer patients are taking selenium on their own than originally anticipated.
2) IRB and Human Subject approval at each affiliated clinic is more time-consuming than estimated.
3) The requirement for snap-frozen tissue has limited study accrual.

Action has been taken to increase recruitment and randomization. Plans for increased recruitment are currently being implemented as noted below:

Recruiting additional urology clinics - IRB applications and approvals are being actively monitored to ensure that each clinic site has all necessary documents as rapidly as possible (Appendix IV). In some cases, the Tucson Coordinating Center (TCC) completes IRB approval forms for the clinics that want to join the study. This speeds the overall approval process by ensuring timely and accurate completion and submission to the appropriate review agencies. As soon as a new clinic has the necessary IRB documentation, the TCC will submit a letter to the DOD for approval for that site.

Advertising/Seminars - in the Tucson and surrounding areas for participants, visiting local military bases and/or sending information in veterans' newsletters regarding the study, and traveling to prostate cancer symposia and urologists' seminars to increase awareness about our trial.

We have recruited nine participants to the study, of which three did not meet the eligibility criteria and one decided not to continue. Therefore, we have five successfully randomized participants. All participants are from the Tucson, AZ clinic.

Participants are randomized into one of three treatment groups (placebo, 200 μg selenium or 400 μg selenium), and are given supplements in six-month supplies.

As mentioned, our decision to require participating urologists to provide frozen sections of biopsy and prostatectomy specimens greatly limited study accrual. This decision was made for a very good reason: frozen tissue can be analyzed for RNA activity; paraffin embedded tissue, given present technology, cannot. Thus, the use of frozen tissue would have enabled us to do all we originally proposed, and a good deal more. Unfortunately, requiring frozen

tissue severely limited urologist participation. Therefore, we have reluctantly decided to rely on paraffin-embedded tissue, which will allow us to use immunohistochemical staining to evaluate apoptosis, proliferation, and the expression of thioredoxin and thioredoxin reductase. It will also allow us to examine the expression of bcl-2 and P-53. Some of our collaborating sites routinely process their tissue by snap-freezing the biopsy and prostatectomy specimens. We will continue to collect snap-frozen material from these sites.

Task 3: Baseline Data Collection

At time of enrollment, we collect a signed informed consent form, paraffin-embedded biopsy slides or two snap-frozen biopsy cores (depending on the standard processing practice of each urology site), pathology reports, Registration, Baseline and Food Frequency questionnaires, plus a blood sample.

Task 4: Follow-Up

Participants have their blood drawn at their study visits once a month for the first two months and then semi-annually thereafter. Additionally, they will receive their assigned study supplement and complete follow-up and urological symptoms questionnaires. The questionnaires ascertain information such as any new illnesses, medications, or adverse events. In addition, the participants will complete additional Food Frequency Questionnaires.

Task 5: Laboratory Analyses

We are conducting PSA analyses at the Tucson Coordinating Center using the Abbot IMx procedure. Blood samples collected from the SELECT Trial participants are sent to Cornell University for Se assays and to the San Diego VA Medical Center for Chromagranin A assays.

In addition to the above noted assays, blood samples are sent to SmithKline Beecham (now part of Quest Diagnostics) for elevated kidney and liver function analyses. This ensures that Selenium is being safely administered to each participant. Plasma alpha tocopheral and lycopene are also archived from the blood draws for future analyses.

Our collaborators are well versed in performing the various proposed analyses on paraffin-embedded tissues. We have worked tissue for Bcl-2, P53, the proliferation antigen Ki67, and the TUNEL assay for apoptosis. We have obtained a monoclonal antibody specific for thyrodoxin and a polyclonal specific thyroredoxin reductase.

Included is an example of the KA2 basal cell specific antibody (Figure 1, A, B) and an example of the positive control and a specimen using the Ki67 (MIB1) antibody (Figure 1 C, D).

Task 6: Data Entry

All forms, questionnaires, and laboratory results are being entered into the database by the trained coordinators and laboratory assistants. Data will be checked semi-annually during Quality Control reviews.

Task 7: Data Analyses and Report Writing

During the last months of the funding period, analyses of the collected data will be performed and reports and manuscripts for publication will be prepared and submitted.

KEY RESEARCH ACCOMPLISHMENTS

No key research accomplishments have been accomplished at this early stage of the clinical trial.

REPORTABLE OUTCOMES

There are no reportable outcomes at this early stage of this clinical trial.

CONCLUSIONS

- Participant enrollment will be accelerated due to ongoing site visits at participating clinics to meet with the collaborating physicians, answer questions and review charts to identify eligible participants.

- Participating urologists will be able to choose to provide paraffin-embedded tissue samples, which will allow more physicians to participate.

REFERENCES

1. Clark LC, Combs GF Jr, Turnbull BW, et al. Effects of selenium supplementation for cancer prevention in patients with carcinoma of the skin. A randomized controlled trial. Nutritional Prevention of Cancer Study Group [see comments] [published erratum appears in JAMA 1997 May 21;277(19):1520]. *JAMA.* 1996;276:1957-63. COMMENTS: Comment in: JAMA 1996 Dec 25;276(24):1984-5, Comment in: JAMA 1997 Mar 19;277(11):880; discussion 881, Comment in: JAMA 1997 Mar 19;277(11):880-1; discussion 881.

APPENDICES

Appendix I – Clinical Trial Questionnaires
Appendix II – Procedures Manual
Appendix III – Data Entry program
Appendix IV – Summary of IRB Approval Status
Appendix V – Figure 1, C, D
Appendix VI – Larry Clark Curriculum Vitae
Appendix VII – James Marshall Curriculum Vitae

WHAT IF I WANT TO WITHDRAW?

You are free to ask questions at any time throughout the study, and you may withdraw from the study at any time without adversely affecting your medical care.

HOW DO I FIND OUT MORE?

If you are interested in joining the study or would just like to find out more information, please call 1-800-243-6519 outside of Tucson, or 321-7798 within the Tucson area and ask to speak to a SELECT coordinator. We will then send you an information packet and contact your urologist to explain the study to him or her. You can also check out our website at www.selenium.arizona.edu

Thank you for taking the time to find out more about the **SELECT Study, A Chemoprevention Trial of Selenium and Prostate Cancer**

This brochure was produced by the Selenium and Cancer Projects, Larry C. Clark, Principal Investigator, within the Arizona Cancer Center at the University of Arizona, 2504 E. Elm St., Tucson, AZ 85716. www.selenium.arizona.edu

SELECT

STUDY

CHEMOPREVENTION TRIAL OF SELENIUM AND PROSTATE CANCER

LARRY C. CLARK, M.P.H., PH.D.

ARIZONA®
CANCER CENTER

TRIAL BACKGROUND

Dr. Larry Clark developed the idea for this trial after reporting the results of the Nutritional Prevention of Cancer (NPC) Trial. This trial observed a decrease in the incidence of prostate cancer for the participants who were taking 200 mcg of selenium per day compared to those taking a placebo.

In this new SELECT study, we want to look at how selenium affects the prostate and have a better understanding of the potential effect that selenium may have on prostate cancer.

STUDY SUMMARY

The purpose of this trial is to assess if treatment with the essential nutrient Selenium slows the advancement of prostate cancer. Different doses of selenium will be given to participants during the study.

Participants in the SELECT study will have a 66% chance of taking SElenium and can ELECT their cancer treatment of either Watchful Waiting or Prostatectomy.

Eligible patients will be randomly placed into one of three groups. Two groups will be given selenium at dosages of either 200 or 400 micrograms. The third group will be given a placebo pill that looks and smells exactly like a selenium pill, but contains no selenium. This placebo group will serve as the control group so that the effect of selenium in the other groups can be clearly determined.

WHAT DOES SELENIUM DO?

The major functions of selenium in the body that have been discovered to date include:

- Selenium helps repair damage to DNA. DNA carries our genetic information and damage to it may increase the risk of cancer.
- Selenium is found in enzymes that may help decrease the spread of damage to cells by promoting a process called apoptosis.
- At high doses, selenium may decrease the rates of tumor growth.
- Selenium appears to improve the functioning of the immune system and its response to infections.

WHAT IS SELENIUM?

Selenium is a nutritionally essential trace element that occurs naturally in the soil. The amount of selenium in the soil varies greatly by region. It enters our bodies through our food (both plant and animal products) and, to a lesser extent, water sources. It enters the food chain when plants absorb selenium from the soil into their leaves, stems, seeds, and fruits. Animals eat plants containing the selenium, and this is stored in their tissues. Some foods that are good sources of selenium are grains grown in the Midwestern United States and animal meats, especially organ meats. Certain foods like brazil nuts are especially high in selenium.

WHO IS ELIGIBLE TO JOIN?

You may be eligible to join this study if you:

- ✓ Have been recently diagnosed with prostate cancer.
- ✓ Have a current PSA below 50 ng/ml;
- ✓ Have received no therapy (hormones, surgery, or radiation) and are engaged in watchful waiting, or will choose to have a prostatectomy;
- ✓ Are free of any symptomatic metastatic prostate cancer;
- ✓ Have no history of any other internal malignancy within the last 5 years;
- ✓ Are between 45 and 80 years old; and
- ✓ Are not taking more than 50 micrograms per day of selenium from other sources.
- ✓ Are not taking Propecia or Proscar.

WHAT WILL I HAVE TO DO?

If you join this study, you will agree to:

- ✓ Take one tablet every day for up to three years.
- ✓ Give a blood sample every month for the first two months, then semi-annually for the rest of the study.
- ✓ Provide information on your nutrition and mood status periodically.
- ✓ Visit your urologist twice a year.
- ✓ Report any new medication, illnesses, or hospitalizations.

SELECT

Thank You!

Thank you for taking the time to look at the enclosed information concerning our new study:

SELECT: Chemoprevention Trial of Selenium and Prostate Cancer.

Our current trial, the ***Nutritional Prevention Of Cancer Project***, indicates that male study participants taking 200 micrograms of selenium have a decreased incidence of prostate cancer when compared to participants not taking selenium.

This new project will attempt to determine if selenium is beneficial to participants who have prostate cancer.

Included in this letter are the following items:

- ✓ **A Study Summary**
- ✓ **A Participant Information Sheet**

If any of these items are missing, please call 1-800-243-6519, and ask to speak with a SELECT study coordinator. Within the Tucson area, please call 321-7798.

SELECT: Chemoprevention Trial of Selenium and Prostate Cancer

SUMMARY OF STUDY

The purpose of this trial is to assess the potential of treatment with the essential trace element **selenium (Se)** at various doses to inhibit the progression of prostate cancer.

Eligible participants will be randomly placed into one of three groups. Two of these groups will be given selenium at dosages of either 200 or 400 micrograms. The third group will be given a placebo pill that looks and smells exactly like a selenium pill, but has no selenium in it. The placebo group will serve as the control group so that the effect of selenium in the other groups can be clearly determined.

There will be at least 110 participants involved in this study. Results of Prostate-Specific Antigen (PSA) tests can be made available through participants' physicians only. Selenium results will not be available to study participants due to the double-blind design of the trial. The background for this study was provided from the Nutritional Prevention of Cancer (NPC) study.

SELECT

SELECT: Chemoprevention Trial of Selenium and Prostate Cancer

PARTICIPANT INFORMATION SHEET

The purpose of this research study is to test the possibility that a supplement of the trace element selenium can slow the growth of prostate cancer, and to determine if the supplement is effective in patients who have had a prostatectomy. This trial has the opportunity to assess the potential benefit of selenium supplementation at nutritional doses on the progression of prostate cancer.

The advantage of selenium supplementation therapy is its relative non-toxicity. Additionally, selenium may improve the mood of participants and it can either diminish the growth rate of prostate cancers or induce regression of existing cancers.

To participate in this study, patients will undergo a screening procedure to ensure eligibility. This will entail a physical examination by their urologist including a rectal exam and blood tests to ensure normal liver and kidney function. To be eligible, participants must have a biopsy-proven carcinoma and have elected "watchful waiting" after their diagnosis or have chosen to undergo a prostatectomy. Patients meeting the admission criteria will be contacted by a SELECT study coordinator, enrolled into the trial, and monitored for a period of up to three years.

(continued)

Participants will be randomized to take either a placebo or one of two selenium dosages. This means that 66% of participants will receive a selenium supplement. A six-month supply of tablets will be dispensed upon entry into the trial.

If participants report symptoms of selenium toxicity such as unexplained garlic breath or changes in their nails or hair they will be asked about any symptoms that may be related to selenium toxicity and provide a blood sample. No evidence of selenium toxicity has been observed in the previous trial as indicated by routine examination of the participants' nails and hair. Furthermore, no participants withdrew from the study due to medical problems.

There will be no loss of benefit or change in treatment for their prostate cancer whether or not the patients decide to take part in this study. Participants are free to withdraw from the study at any time.

SELECT—Participant Pill Instructions

- Take ***one*** pill at the ***same time*** each day. For example, if you take one pill at 8:00 AM on Monday, then take it as close as possible to 8:00 AM on Tuesday.

- Note: the pills are labeled with the day of the week to help you remember taking your pill.

Here's some hints to using this system:

Think of your blister pack of pills as a mini-calendar. The rows represent the weeks you are taking the pills (week 1, week 2, etc) and the columns are the days of the week.

You will take your first pill from the first row on the day of the week you begin. – make sure that you take the pill from the column corresponding to that day of the week! For example, if you start on a Wednesday, find the pill in the first row, third column, (for Wednesday) and take that pill.

Continue taking the pills by going through the rows from left to right. When you reach the very last row of the blister packet, you can go back to the remaining days on the first row (back to your first 'week') that preceded your first pill and take those pills on the corresponding days of the week.

- If you miss the time for taking your study pill for ***one day***, skip that dose. Then, double the dose the next day.

- If you miss taking the pill for ***5 days in a row or more***, please contact your research coordinator at 1-800-243-6519, or 321-7798 in the Tucson area, to notify us.

- If you have any unused study pills remaining when you receive these pills, please discard them and begin taking the new study pills.

- Please record the date that you take your first pill from a new box of pills. ***(Please write the date on the pill box label in the space provided AND write the date on the pill postcard enclosed and place it in the mail immediately).***

- If you have any questions or concerns, please call your coordinator at: **1-800-243-6519** (outside the Tucson area), **or 321-7798** (in the Tucson area)

SELECT TRIAL - REGISTRATION

Chemoprevention Trial of Selenium and Prostate Cancer (SELECT)

Name: _____ Date: ____/____/____
(Last) (First) (M.I.)

Date of Birth: ____/____/____ Social Security Number: _____

Mailing Address: _____ Home Phone: (____) _____

_____ Work Phone: (____) _____

_____

Registered by: _____ Doctor Name: _____

* * * * * * * * * * * * * * *

CRITERIA FOR ELIGIBILITY (BEFORE BIOPSY):

For the patient to be eligible for the study, all items in the checklist must be answered affirmatively and verified by medical record review. This patient is eligible for the study if he:

1	Has a current PSA of less than 50 ng/ml? **PSA LEVEL=** **NG/ML**	YES	No
2	Has no history of treatment for an internal malignancy in the previous five years?	YES	No
3	Is taking less than 50 micrograms of selenium a day as a daily supplement (including in multivitamin supplements)?	YES	No
4	Has liver and kidney enzymes less than 2 times the upper limit of normal?	YES	No
5	Is a surgical candidate?	YES	No
6	Is less than 80 years of age?	YES	No
7	Has not started taking Proscar within the last three months? (Date started taking ____/____/____)	YES	No

CRITERIA FOR ELIGIBILITY (AFTER BIOPSY):

8	Has a biopsy proven adenocarcinoma of the prostate? **DATE:** ____/____/____	YES	No
9	Has received no therapy (hormones, surgery, or radiation) for prostate cancer and will be followed with watchful waiting or has chosen a prostatectomy?	YES	No
10	Is free of any symptomatic metastatic prostate cancer?	YES	No

Date of next appointment: ____/____/____ Date of biopsy: ____/____/____

Date of blood draw #1: ____/____/____ Gleason Score: _____

Physician's Signature_____ Date_____

1. **If pills are dispensed to the participant at the clinic:** Upon completion of this form, please write the participant ID# from the pill box in the space below *(located at the top left of pill label)*, and fax to the Tucson Coordinating Center (TCC) at 520-321-7774.
2. **If pills are sent from the Tucson Coordinating Center:** Upon completion of this form, please fax this document to the TCC at (520) 321-7774. The TCC will fax the form back with a Participant ID number.

Participant ID#:_____

Chemoprevention Trial of Selenium and Prostate Cancer

Date: 07/09/98 initial approval HSC#: 97-57
Amendments: 07/17/98, 07/22/98, 08/06/98, 9/16/98, 10/1/98

I AM BEING ASKED TO READ THE FOLLOWING MATERIAL TO ENSURE THAT I AM INFORMED OF THE NATURE OF THIS RESEARCH STUDY AND OF HOW I WILL PARTICIPATE IN IT, IF I CONSENT TO DO SO. SIGNING THIS FORM WILL INDICATE THAT I HAVE BEEN SO INFORMED AND THAT I GIVE MY CONSENT. FEDERAL REGULATIONS REQUIRE WRITTEN INFORMED CONSENT PRIOR TO PARTICIPATION IN THIS RESEARCH STUDY SO THAT I CAN KNOW THE NATURE AND RISKS OF MY PARTICIPATION AND CAN DECIDE TO PARTICIPATE OR NOT PARTICIPATE IN A FREE AND INFORMED MANNER.

PURPOSE

I am being invited to participate voluntarily in a research study of the use of daily selenium supplements on the increasing growth of prostate cancer. Selenium is an essential trace element which is required as part of the human diet. This double-blind (neither patient nor physician has information concerning assignment to selenium/placebo or dosages), randomized (to assign at random) study is designed to test the possibility that a supplement of selenium can decrease the increasing growth of prostate cancer. In a previous trial consisting of patients with a history of skin cancer, it was observed that patients who were in the selenium supplemented group showed a significantly lower risk of developing prostate cancer. I understand that the purpose of this study is to determine if selenium supplementation will decrease the growth of my prostate cancer and to determine how quickly a positive effect will be seen. I also understand that if I elect to undergo a prostatectomy, the purpose of the study will be to determine if selenium supplementation decreases the occurrence of the spread of my disease. I understand that two dosages of selenium will be used in order to determine the most effective dose for use in slowing the growth of prostate cancer. This study will not use selenium as a treatment option for the possible cure of prostate cancer.

SELECTION CRITERIA

I understand that I am being invited to participate because I have been diagnosed with localized prostate cancer within the last four years and have not yet received any therapy, such as radiation treatment, hormone therapy or surgery. I will be one of at least 110 individuals participating in this study, which will be conducted under Investigational New Drug #29829 from the Food And Drug Administration. The selenium preparations to be used in this study are investigational and not approved by the Food and Drug Administration (FDA) for commercial use; however, the FDA has allowed their use in this research study.

STANDARD TREATMENT

I am being considered for this study because I have declined immediate active treatment for my prostate cancer and have elected to Awatch≅ for cancer growth prior to any treatment intervention. I will also be considered for participation in this study if I choose to have a prostatectomy. I understand that if I choose to have no therapy for my cancer, there is the possibility that my cancer will spread to other parts of my body. If I decide not to participate in this study, I may elect to continue no treatment for my cancer and wait for any possible changes. Other treatment options are hormone therapy or radiation therapy. I am aware that

I will need to consult my regular physician to discuss these treatment options.

PROCEDURE(S)

If I agree to participate, I will be asked questions about my health habits (such as smoking), a history of medical problems and current use of vitamins and medications. I will have a complete physical examination by my physician, including rectal exam. I must have a biopsy-proven (removal and analysis of tissue) prostate cancer. Tissue samples from my biopsies will be forwarded for analysis to the investigators participating in this study. A blood sample of approximately 21 cc. (1 1/2 tablespoons) will be collected from me at the beginning of the study and quarterly thereafter at scheduled visits to my physician. The amount of selenium in these samples will be measured in addition to the level of prostate specific antigen (PSA). I understand that there is a possibility that the blood and tissue samples which I am providing under this study may also be used in other prostate cancer research studies and could potentially have some commercial applicability if warranted by new scientific or medical information. Future research with collected specimens will be conducted under an IRB (Internal Review Board) approved protocol.

I will be contacted once a month for the first three months and quarterly thereafter by a study coordinator at the Project Coordinating Center in Tucson, AZ. I will be asked about my general well-being, and to report any new illness requiring a physician's care, new medications which I am taking, and any hospitalizations. I will also be queried regarding signs of Brewer's yeast intolerance or allergies, or symptoms of selenium toxicity. If I am hospitalized, I give my permission for the study investigators to obtain my medical records in order to determine the reasons for my hospitalization and the treatments which I received. This information will remain confidential. Subjects are monitored for all new illnesses and symptoms, since there is always the possibility that unknown benefits or side effects could occur, which can only be detected in double blind clinical trials. I will also be examined at least semi-annually by my urologist.

After I am enrolled in the study I will be assigned by chance to one of three groups: one group will receive a 400 microgram dose of selenium daily in a yeast tablet, one group will receive a 200 microgram dose of selenium daily in a yeast tablet, and the remaining group will receive a placebo yeast tablet. Placebo tablets are made up of Brewer's yeast (without the additional selenium which are in the selenium supplements) and are identical in size and appearance to selenium tablets. The group of patients taking the placebo tablets will serve as the control group for the study. I will take these tablets daily for up to three years. Neither myself nor my physician will know my supplementation group assignment, although this information may be given to my physician if it is medically necessary or in the event of an emergency. I will have a 2 in 3 chance (66%) of receiving selenium supplements in this trial. I will be mailed a 6 month supply of tablets at randomization (when I am assigned at random to either selenium or placebo and to which dosage of selenium) and twice per year thereafter.

I will be asked to participate in this study for approximately 2 ½ years.

Chemoprevention Trial of Selenium and Prostate Cancer

Date: 07/09/98 initial approval HSC#: 97-57
Amendments: 07/17/98, 07/22/98, 08/06/98, 9/16/98, 10/1/98

RISKS

There are no known consequences to my health if I am assigned to the placebo group, since it contains only Brewer's yeast. If I am assigned to one of the selenium groups I understand that there is a risk that I could develop side effects including garlic breath, nail brittleness and hair breakage. If I believe that I have developed these or other symptoms related to the selenium supplementation, I may request the study center to decrease my dose and still remain an active participant in the project. In a study conducted in China, adverse side effects have been observed in a small percentage (10%) of Chinese subjects who had consumed a diet with over 1,000 microgram selenium daily. Individuals with chronic or prolonged high selenium intakes above those used in this trial have reported the development of "pins and needles" sensations, skin rash, irritability, weakness, nausea, or vomiting.

There may be some pain from the needle stick required to obtain my blood for evaluation, and some bruising at the needle site, or other minor complications from blood sample collection.

If I have hair or nail changes, I will visit a project dermatologist who will examine, sample and photograph them. These photographs will be used to observe the effects of selenium on hair and nails.

BENEFITS

I may not receive any benefit from participation on this study, beyond the regular monitoring of my PSA.

CONFIDENTIALITY

I understand that my medical records will become part of my research file and will remain confidential, but the information will be available to, and will be analyzed by, the investigators and institutions participating in this study. Also, the Food and Drug Administration may inspect these records at any time. I will not, however, be personally identified in any publication of the results of this study.

It should be noted that representatives of the U.S. Army Medical Research and Materiel Command are eligible to review research records as a part of their responsibility to protect human subjects in research.

I will be contacted periodically by the project investigators to obtain additional new information which may be important for the project. I also understand that my doctor may ask me to withdraw from the study for scientific reasons or for my safety; for example, if I develop side effects or other medical problems.

PARTICIPATION COSTS AND SUBJECT COMPENSATION

Should I be injured as a direct result of participating in this research project, I will be provided medical care, at no cost to me, for that injury. I will not receive any injury compensation, only medical care. I also understand that this is not a waiver or release of my legal rights. I should discuss this issue thoroughly with the principal investigator before I enroll in this study.

I will be responsible for the usual costs of treatment and the costs of my regularly scheduled clinic visits (including transportation, clinic fees, physician's fees, biopsy (removal and analysis of tissue), bone scan and laboratory fees, etc.), but I will not be charged for the supplement (tablets) or placebo or for the laboratory tests relating to this study protocol. I will not be paid for participating in this study.

LIABILITY

Side effects or harm are possible in any research program despite the use of high standards of care and could occur through no fault of mine or the investigator involved. Known side effects have been described in this consent form. However, unforeseeable harm also may occur and require care. I do not give up any of my legal rights by signing this form. In the event that I require or am billed for medical care that I feel has been caused by the research, I should contact the principal investigator, Larry C. Clark, M.P.H., Ph. D., at (520) 321-7798. If I have questions regarding my rights as a research subject, I may call the Human Subjects Committee Office, University of Arizona, Tucson, Arizona, 520-626-6721.

I understand that I can ask my urologist or the project coordinator at the Patient Coordinating Center (phone 520-321-7798) any questions that I may have about the study. They will answer any further questions I may have at any time concerning the study, procedures, or any illnesses or injuries that may appear to be related to the study.

VOLUNTEER REGISTRY DATA BASE REQUIREMENTS

I understand that the U.S. Army Medical Research and Materiel Command has sponsored this research. I also understand that it is the policy of the U.S. Army Medical Research and Materiel Command that data sheets are to be completed on all volunteers participating in research for entry into this Command's Volunteer Registry Data Base. The information to be entered into this confidential data base will include my name, address, Social Security number, study name and dates. The intent of the data base is two-fold: first, to readily answer questions concerning an individual's participation in research sponsored by USAMRMC; and second, to ensure that the USAMRMC can exercise its obligation to ensure research volunteers are adequately warned (duty to warn) of risks and to provide new information as it becomes available. The information will be stored at USAMRMC for a minimum of 75 years.

Date: 07/09/98
07/17/98 amended

HSC#: 97-57

Chemoprevention Trial of Selenium and Prostate Cancer

AUTHORIZATION

BEFORE GIVING MY CONSENT BY SIGNING THIS FORM, THE METHODS, INCONVENIENCES, RISKS, AND BENEFITS HAVE BEEN EXPLAINED TO ME AND MY QUESTIONS HAVE BEEN ANSWERED. I UNDERSTAND THAT I MAY ASK QUESTIONS AT ANY TIME AND THAT I AM FREE TO WITHDRAW FROM THE PROJECT AT ANY TIME WITHOUT CAUSING BAD FEELINGS OR AFFECTING MY MEDICAL CARE. MY PARTICIPATION IN THIS PROJECT MAY BE ENDED BY THE INVESTIGATOR OR BY THE SPONSOR FOR REASONS THAT WOULD BE EXPLAINED. NEW INFORMATION DEVELOPED DURING THE COURSE OF THIS STUDY WHICH MAY AFFECT MY WILLINGNESS TO CONTINUE IN THIS RESEARCH PROJECT WILL BE GIVEN TO ME AS IT BECOMES AVAILABLE. I UNDERSTAND THAT THIS CONSENT FORM WILL BE FILED IN AN AREA DESIGNATED BY THE HUMAN SUBJECTS COMMITTEE WITH ACCESS RESTRICTED TO THE PRINCIPAL INVESTIGATOR, LARRY C. CLARK, M.P.H., PH.D. OR AUTHORIZED REPRESENTATIVE OF THE ARIZONA CANCER CENTER. I UNDERSTAND THAT I DO NOT GIVE UP ANY LEGAL RIGHTS BY SIGNING THIS FORM. A COPY OF THIS SIGNED CONSENT FORM WILL BE GIVEN TO ME.

_____ _____

Subject's Signature Date

_____ _____

Witness' Signature Date

INVESTIGATOR=S AFFIDAVIT

I hereby certify that to the best of my knowledge the person who is signing this consent form understands clearly the nature, demands, benefits, and risks involved in his/her participation and his/her signature is legally valid. A medical problem or language or educational barrier has not precluded this understanding.

_____ _____

Signature of Investigator Date

I certify that this is an accurate and true translation.

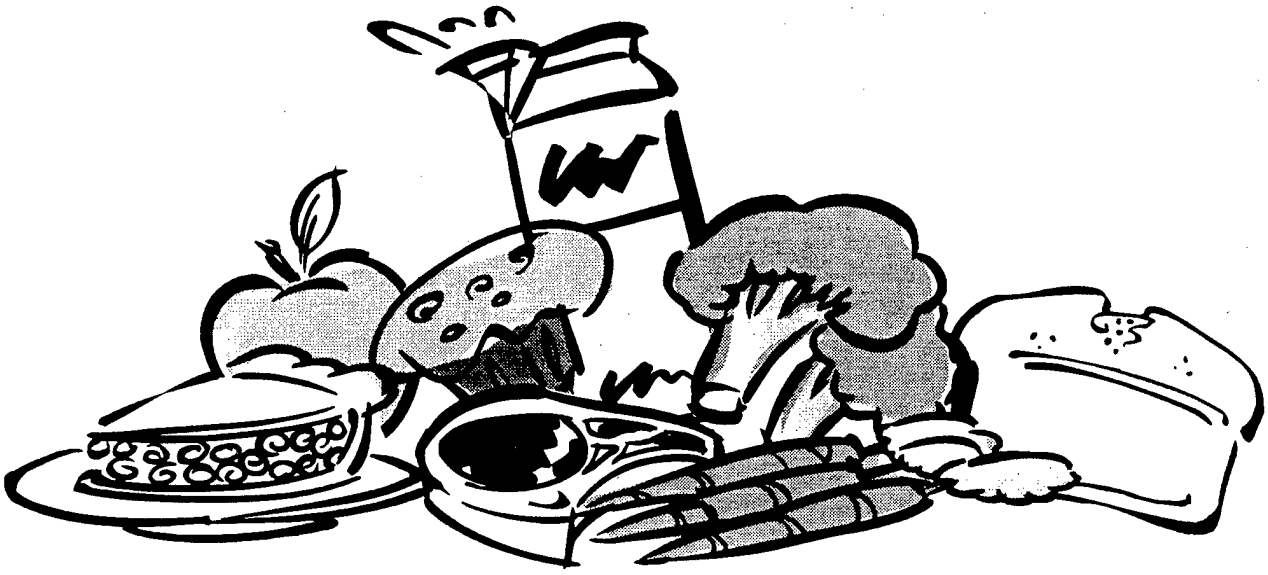
_____

Lori Fischbach, M.P.H., Ph.D.
2504 E. Elm St
520-321-7798 tel
520-321-7774 fax

_____

Initials Date

FOOD QUESTIONNAIRE



This form asks about your usual food intake during _____.
It takes about 30-45 minutes to complete. Please follow these instructions:

- Answer each question as best you can -- estimate if you aren't sure.
- USE PENCIL.
- Be certain to completely blacken in each of your answers, and erase completely if you make any changes.
- Do not make any other marks on this form. If you wish to make comments, please use a separate piece of paper.

Please print your name in this box. Please do not write outside the boxed area.

DATE				
MO		DAY		YR
				9

SEX

- ○ Male
- ○ Female

AGE

- ○ Less than 20
- ○ 20-29
- ○ 30-39
- ○ 40-49
- ○ 50-59
- ○ 60-69
- ○ 70+

IDENTIFICATION NUMBER

PLEASE MAKE NO MARKS IN THIS AREA

708571

Answer each question completely. Some questions have more than one part as shown in the example below. Make sure you complete all parts of the question.

Example: This person ate oil-packed tuna. It was usually prepared as tuna salad or tuna noodle casserole.

4. Did you eat canned tuna during this time period?
- ○ No (Go to question 5.)
- ● Yes

4.1 When you ate canned tuna was it usually . . .
- ○ Water-packed
- ● Oil-packed
- ○ Either one
- ○ Don't know

4.2 When you ate canned tuna how was it usually prepared? (Mark one or two.)
- ○ Tuna, plain
- ● Tuna salad with mayonnaise
- ● Tuna noodle casserole

These questions ask about the foods you ate during _____

1. Did you eat chicken or turkey during this time period?
- ○ No (Go to question 2.)
- ○ Yes

1.1 When you ate chicken or turkey, how often did you eat the skin?
- ○ Almost always
- ○ Often
- ○ Sometimes
- ○ Rarely
- ○ Never

1.2 Did you usually choose . . .
- ○ Light meat
- ○ Dark meat
- ○ Both

2. Did you eat beef, pork or lamb during this time period?
- ○ No (Go to question 3.)
- ○ Yes

2.1 When you ate beef, pork or lamb, how often did you eat the fat?
- ○ Almost always
- ○ Often
- ○ Sometimes
- ○ Rarely
- ○ Never

3. Did you eat hamburger or other ground meat during this time period?
- ○ No (Go to question 4.)
- ○ Yes

3.1 When you ate hamburger or other ground meat, was it usually . . .
- ○ Regular
- ○ Lean
- ○ Extra lean
- ○ Ground turkey
- ○ Don't know

4. Did you eat canned tuna during this time period?
- ○ No (Go to question 5.)
- ○ Yes

4.1 When you ate canned tuna was it usually . . .
- ○ Water-packed
- ○ Oil-packed
- ○ Either one
- ○ Don't know

4.2 When you ate canned tuna how was it usually prepared? (Mark one or two.)
- ○ Tuna, plain
- ○ Tuna salad with mayonnaise
- ○ Tuna noodle casserole

5. Did you drink milk or beverages made with milk, such as hot chocolate, during this time period? (Do not include milk used on cereal or in coffee or tea.)

○ No (Go to question 6.) ○ Yes

5.1 When you drank milk or milk beverages, was it usually . . .

- ○ Whole milk
- ○ 2% milk
- ○ 1% milk or buttermilk
- ○ Non-fat or skim milk
- ○ Evaporated or condensed milk
- ○ Soy milk
- ○ Don't know

6. Did you use milk, cream or creamer on cereal during this time period?

○ No (Go to question 7.) ○ Yes

6.1 When you used milk, cream or creamer on cereal, what type did you usually use? (Mark one or two.)

- ○ Cream or half and half
- ○ Whole milk
- ○ 2% milk
- ○ 1% milk
- ○ Non-fat or skim milk
- ○ Evaporated or condensed milk
- ○ Soy milk
- ○ Non-dairy creamer
- ○ Don't know

7. Did you use milk, cream or creamer in coffee or tea during this time period?

○ No (Go to question 8.) ○ Yes

7.1 When you used milk, cream or creamer in coffee or tea, what type did you usually use? (Mark one or two.)

- ○ Cream or half and half
- ○ Whole milk
- ○ 2% milk
- ○ 1% milk
- ○ Non-fat or skim milk
- ○ Evaporated or condensed milk
- ○ Soy milk
- ○ Non-dairy creamer
- ○ Don't know

8. Did you eat cold cereals during this time period?

○ No (Go to question 9.) ○ Yes

8.1 When you ate cold cereals, what type did you usually eat? (Mark one or two.)

- ○ Granola cereals
- ○ High-fiber or bran cereals, such as FiberOne®, Raisin Bran®
- ○ Whole grain cereals such as Cheerios®, Shredded Wheat®
- ○ Fortified cereals such as Total®, Product 19®
- ○ Other cereals such as corn flakes, Frosted Flakes®

9. Did you eat okra, squash, or yams during this time period?

○ No (Go to question 10.) ○ Yes

9.1 When you ate okra, squash, or yams, how often were they fried? (Do not include potatoes.)

- ○ Almost always
- ○ Often
- ○ Sometimes
- ○ Rarely
- ○ Never

10. What kinds of fat did you usually use to deep fry, pan fry or sauté foods? (Mark one or two.)

- ○ Stick margarine
- ○ Tub margarine
- ○ Butter
- ○ Shortening (Crisco®, lard, bacon fat or drippings, salt pork, ham hock)
- ○ Olive or canola oil
- ○ Other oils (vegetable, corn, peanut, safflower)
- ○ Non-stick spray (Pam®)
- ○ Didn't add fat

PLEASE MAKE NO MARKS IN THIS AREA

708571

11. What kinds of fat did you usually add <u>when</u> cooking beans, rice, vegetables and potatoes? (Mark one or two.)

- ○ Low calorie margarine
- ○ Stick margarine
- ○ Tub margarine
- ○ Butter
- ○ Shortening (Crisco®, lard, bacon fat or drippings, salt pork, ham hock)
- ○ Olive or canola oil
- ○ Other oils (vegetable, corn, peanut, safflower)
- ○ Non-stick spray (Pam®)
- ○ Didn't add fat

12. What kinds of fat did you usually add <u>after</u> cooking vegetables, beans, rice and potatoes? (Mark one or two.)

- ○ Low calorie margarine
- ○ Stick margarine
- ○ Tub margarine
- ○ Butter
- ○ Sour cream
- ○ Olive or canola oil
- ○ Other oils (vegetable, corn, peanut, safflower)
- ○ Didn't add fat

13. What kinds of fat did you usually use on breads, muffins, tortillas and rolls? (Mark one or two.)

- ○ Low calorie margarine
- ○ Stick margarine
- ○ Tub margarine
- ○ Butter
- ○ Olive or canola oil
- ○ Other oils (vegetable, corn, peanut, safflower)
- ○ Didn't add fat

14. Did you make your own tortillas during this time period?

○ No (Go to question 15.) ○ Yes

14.1 When you made tortillas, did you make them with lard, shortening, or other fat?

- ○ Yes, made with fat.
- ○ No, made without fat.

15. What type of salad dressing did you usually use?

- ○ Regular, such as French or oil and vinegar
- ○ Low-fat (diet)
- ○ Fat-free (no oil)
- ○ Didn't use salad dressing

16. What type of mayonnaise did you usually use?

- ○ Regular
- ○ Low-fat (diet)
- ○ Fat-free
- ○ Didn't use mayonnaise

17. Did you eat popcorn during this time period?

○ No (Go to question 18.) ○ Yes

17.1 What type of popcorn did you usually eat?

- ○ Popped in oil, pre-popped, or at movies
- ○ Regular microwave
- ○ Air-popped or special "lite" microwave

17.2 When you ate popcorn, how often did you add butter or margarine?

- ○ Almost always
- ○ Often
- ○ Sometimes
- ○ Rarely
- ○ Never

18. Did you eat cookies during this time period?

○ No (Go to question 19.) ○ Yes

18.1 When you ate cookies, how often were they graham crackers, vanilla wafers, fig bars, or special *low fat* or *no fat* cookies?

- ○ Almost always
- ○ Often
- ○ Sometimes
- ○ Rarely
- ○ Never

19. Did you eat cakes or other pastries during this time period?

○ No (Go to next page.) ○ Yes

19.1 When you ate cakes or other pastries, how often were they angel food cakes, sponge cakes, or special *low fat* or *no fat* cakes or pastries?

- ○ Almost always
- ○ Often
- ○ Sometimes
- ○ Rarely
- ○ Never

The next section is about how often you usually eat specific foods.

First: Mark the column to show how often, on average, you ate the food.
Second: Mark your usual serving size as small, medium or large.

Please note:

- A small serving is about one-half (1/2) the medium serving size, or less.
- A large serving is about one-and-a-half (1 1/2) times the medium serving size, or more.
- If you never ate a food, mark "Never or less than once per month," and omit the serving size altogether.
- Please *do not skip* any foods.

Example: This person ate a medium serving of rice about twice per month and never ate sausage.

TYPE OF FOOD	HOW OFTEN DID YOU EAT THE FOOD (Mark one)									AMOUNT			
	Never or less than once per month	1 per month	2-3 per month	1 per week	2 per week	3-4 per week	5-6 per week	1 per day	2+ per day	Medium Serving Size	Your Serving Size S	M	L
Rice	○	○	●	○	○	○	○	○	○	3/4 cup	○	●	○
Sausage	●	○	○	○	○	○	○	○	○	2 slices or 2 ounces	○	○	○

During _____ . . .

TYPE OF FOOD	HOW OFTEN DID YOU EAT THE FOOD (Mark one)									AMOUNT			
	Never or less than once per month	1 per month	2-3 per month	1 per week	2 per week	3-4 per week	5-6 per week	1 per day	2+ per day	Medium Serving Size	Your Serving Size S	M	L
FRUITS AND JUICES													
Apples and pears	○	○	○	○	○	○	○	○	○	1 medium or 1/2 cup	○	○	○
Bananas	○	○	○	○	○	○	○	○	○	1 medium	○	○	○
Peaches, nectarines and plums (fresh or canned)	○	○	○	○	○	○	○	○	○	1 medium or 1/2 cup	○	○	○
Cantaloupe, orange melon, muskmelon, mango and papaya	○	○	○	○	○	○	○	○	○	1/4 melon or 1 cup	○	○	○
Watermelon and red melon	○	○	○	○	○	○	○	○	○	1 medium slice or 1 cup	○	○	○
All other melon, such as honeydew	○	○	○	○	○	○	○	○	○	1 medium slice or 1 cup	○	○	○
Apricots (fresh, canned, or dried)	○	○	○	○	○	○	○	○	○	2 medium or 4 halves	○	○	○
Other dried fruit, such as raisins and prunes	○	○	○	○	○	○	○	○	○	1/4 cup	○	○	○
Oranges, grapefruit and tangerines (not juice)	○	○	○	○	○	○	○	○	○	1 orange or 1/2 grapefruit	○	○	○
Strawberries and kiwi	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Any other fruit, such as fruit cocktail, berries, grapes, applesauce, pineapple	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○

708571

PLEASE MAKE NO MARKS IN THIS AREA

TYPE OF FOOD	HOW OFTEN DID YOU EAT THE FOOD (Mark one)									AMOUNT			
	Never or less than once per month	1 per month	2-3 per month	1 per week	2 per week	3-4 per week	5-6 per week	1 per day	2+ per day	Medium Serving Size	Your Serving Size S	M	L
Orange juice and grapefruit juice	○	○	○	○	○	○	○	○	○	6 ounce glass	○	○	○
Tang®, Kool-Aid®, Hi-C®, and other fruit drinks	○	○	○	○	○	○	○	○	○	6 ounce glass	○	○	○
Other fruit juices such as apple, grape	○	○	○	○	○	○	○	○	○	6 ounce glass	○	○	○
VEGETABLES													
Green or string beans	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Green or English peas	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Refried beans	○	○	○	○	○	○	○	○	○	3/4 cup	○	○	○
All other beans such as baked beans, lima beans, black-eyed peas and chili without meat	○	○	○	○	○	○	○	○	○	3/4 cup	○	○	○
Tofu and textured vegetable products	○	○	○	○	○	○	○	○	○	3 slices or 3 ounces	○	○	○
Avocado and guacamole, including added to mixed dishes	○	○	○	○	○	○	○	○	○	1/4 medium or 1/4 cup	○	○	○
Corn and hominy	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Tomatoes, fresh or juice	○	○	○	○	○	○	○	○	○	1 medium or 6 ounce glass	○	○	○
Tomatoes cooked, tomato sauce, salsa and salsa picante	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Green peppers, green chilies, jalapeños, and green chili salsa	○	○	○	○	○	○	○	○	○	1/4 cup	○	○	○
Red peppers and red chilies	○	○	○	○	○	○	○	○	○	1/4 cup	○	○	○
Broccoli	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Cooked greens, such as spinach, mustard greens, turnip greens, collards	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Carrots, including mixed dishes with carrots	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Summer squash, zucchini, nopales, and okra	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Winter squash, such as acorn, butternut, pumpkin	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Coleslaw	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Cauliflower, cabbage, sauerkraut and Brussels sprouts	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Onions and leeks, including in cooking	○	○	○	○	○	○	○	○	○	1/4 cup	○	○	○

TYPE OF FOOD	HOW OFTEN DID YOU EAT THE FOOD (Mark one)									AMOUNT			
	Never or less than once per month	1 per month	2-3 per month	1 per week	2 per week	3-4 per week	5-6 per week	1 per day	2+ per day	Medium Serving Size	Your Serving Size S	M	L
Lettuce and plain lettuce salad	○	○	○	○	○	○	○	○	○	1 medium bowl	○	○	○
Mixed lettuce or spinach salad with vegetables such as carrots or tomatoes	○	○	○	○	○	○	○	○	○	1 medium bowl	○	○	○
Salad dressing, such as Italian, 1000 Island, French (include low-fat and fat-free dressings)	○	○	○	○	○	○	○	○	○	2 tablespoons	○	○	○
Plantains, fried	○	○	○	○	○	○	○	○	○	1 cup	○	○	○
French fries, fried potatoes, fried rice, fried cassava and fritters	○	○	○	○	○	○	○	○	○	3/4 cup	○	○	○
Sweet potatoes and yams	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Other potatoes, cassava, and yucca (boiled, baked, or mashed)	○	○	○	○	○	○	○	○	○	1 medium or 1/2 cup	○	○	○
Potato, macaroni, or pasta salads made with mayonnaise or oil	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Rice, grains and plain noodles	○	○	○	○	○	○	○	○	○	3/4 cup	○	○	○
Butter, margarine, sour cream, oils, or other fat added to vegetables, beans, rice, and potatoes, after cooking	○	○	○	○	○	○	○	○	○	2 pats or 2 teaspoons	○	○	○
MEAT, FISH, POULTRY, LUNCH ITEMS													
Ground meat including hamburgers, meatloaf, and picadillo	○	○	○	○	○	○	○	○	○	1 medium or 3 ounces	○	○	○
Beef, pork and lamb as a main dish, such as steak, roast and ham	○	○	○	○	○	○	○	○	○	4 ounces	○	○	○
Beef, pork and lamb as a sandwich (steak sandwich, BBQ sandwich)	○	○	○	○	○	○	○	○	○	3 ounces	○	○	○
Stew, pot pie and casseroles with meat or chicken	○	○	○	○	○	○	○	○	○	1 cup	○	○	○
Chili with meat and beans	○	○	○	○	○	○	○	○	○	1 cup	○	○	○
Liver, including chicken liver, and other organ meats	○	○	○	○	○	○	○	○	○	4 ounces	○	○	○
Fried chicken	○	○	○	○	○	○	○	○	○	2 small or 1 large piece	○	○	○
Chicken and turkey (roasted, stewed or broiled)	○	○	○	○	○	○	○	○	○	2 small or 1 large piece	○	○	○
Gravies made with meat drippings and white sauce	○	○	○	○	○	○	○	○	○	1/4 cup	○	○	○
Fried fish, fish sandwich, and fried shellfish (shrimp, oysters)	○	○	○	○	○	○	○	○	○	3 ounces or 1 sandwich	○	○	○

TYPE OF FOOD	HOW OFTEN DID YOU EAT THE FOOD (Mark one)									AMOUNT			
	Never or less than once per month	1 per month	2-3 per month	1 per week	2 per week	3-4 per week	5-6 per week	1 per day	2+ per day	Medium Serving Size	Your Serving Size S	M	L
Shellfish, not fried (shrimp, lobster, crab and oysters)	○	○	○	○	○	○	○	○	○	3 ounces or 1/2 cup	○	○	○
Canned tuna, tuna salad, and tuna casserole	○	○	○	○	○	○	○	○	○	1/2 cup tuna or 1 cup casserole	○	○	○
White fish (broiled or baked) such as sole, snapper, cod	○	○	○	○	○	○	○	○	○	3 ounces	○	○	○
Dark fish (broiled or baked) such as salmon, mackerel, bluefish	○	○	○	○	○	○	○	○	○	3 ounces	○	○	○
Macaroni and cheese, lasagna, or noodles with a cream sauce	○	○	○	○	○	○	○	○	○	1 cup	○	○	○
Spaghetti or other noodles with meat sauce	○	○	○	○	○	○	○	○	○	1 cup	○	○	○
Spaghetti or other noodles with tomato sauce (and no meat)	○	○	○	○	○	○	○	○	○	1 cup	○	○	○
Low-fat pizza	○	○	○	○	○	○	○	○	○	2 slices of a 12" pizza	○	○	○
Pizza	○	○	○	○	○	○	○	○	○	2 slices of a 12" pizza	○	○	○
Tamales, with or without meat	○	○	○	○	○	○	○	○	○	1 medium	○	○	○
Chilaquiles	○	○	○	○	○	○	○	○	○	1 cup	○	○	○
Soft quesadilla	○	○	○	○	○	○	○	○	○	1 medium	○	○	○
Crispy quesadilla and chili relleno	○	○	○	○	○	○	○	○	○	1 medium	○	○	○
Soft taco and enchilada baked without oil	○	○	○	○	○	○	○	○	○	2 medium	○	○	○
Flauta and crispy rolled taco	○	○	○	○	○	○	○	○	○	2 medium	○	○	○
Regular burrito and enchilada	○	○	○	○	○	○	○	○	○	1 burrito or 2 enchiladas	○	○	○
Taco and tostada	○	○	○	○	○	○	○	○	○	1 medium	○	○	○
Lunch meat such as ham, turkey and other special lean meats	○	○	○	○	○	○	○	○	○	2 slices	○	○	○
All other lunch meat such as bologna, salami, Spam®, potted and canned meat	○	○	○	○	○	○	○	○	○	2 slices	○	○	○
Hot dogs, chorizo, and other sausage such as bratwurst	○	○	○	○	○	○	○	○	○	2 hot dogs or 3 ounces	○	○	○

708571

PLEASE MAKE NO MARKS IN THIS AREA

TYPE OF FOOD	HOW OFTEN DID YOU EAT THE FOOD (Mark one)									AMOUNT			
	Never or less than once per month	1 per month	2-3 per month	1 per week	2 per week	3-4 per week	5-6 per week	1 per day	2+ per day	Medium Serving Size	Your Serving Size S	M	L
Cream soups such as chowders, potato, tomato, cheese, ajiaco	○	○	○	○	○	○	○	○	○	1 cup or 1 medium bowl	○	○	○
Bean soups such as pea, lentil, black bean, potajes	○	○	○	○	○	○	○	○	○	1 cup or 1 medium bowl	○	○	○
Vegetable soups	○	○	○	○	○	○	○	○	○	1 cup or 1 medium bowl	○	○	○
Menudo and tortilla soup	○	○	○	○	○	○	○	○	○	1 cup or 1 medium bowl	○	○	○
Other soups such as chicken noodle	○	○	○	○	○	○	○	○	○	1 cup or 1 medium bowl	○	○	○
BREADS, SNACKS, SPREADS													
Biscuits, muffins, scones, and croissants	○	○	○	○	○	○	○	○	○	2 biscuits or 1 medium	○	○	○
White breads, including bagels, rolls, pita bread, and English muffins	○	○	○	○	○	○	○	○	○	2 slices or 1 medium	○	○	○
Dark breads, including dark bagels, rolls, pita bread, and English Muffins	○	○	○	○	○	○	○	○	○	2 slices or 1 medium	○	○	○
Corn bread, corn muffins, and cornmeal mush	○	○	○	○	○	○	○	○	○	1 medium or 1/2 cup	○	○	○
Tortillas, corn (not including tacos)	○	○	○	○	○	○	○	○	○	2 medium	○	○	○
Tortillas, flour or wheat (not including tacos)	○	○	○	○	○	○	○	○	○	1 - 12 inch or 2 - 7 inch	○	○	○
Indian fry bread	○	○	○	○	○	○	○	○	○	1 - 9 inch	○	○	○
Snacks such as potato chips, corn chips, tortilla chips, pork skins, Ritz® and cheese crackers	○	○	○	○	○	○	○	○	○	2 handfuls or 1 cup	○	○	○
Saltines, SnackWell's®, fat-free tortilla chips, and fat-free potato chips	○	○	○	○	○	○	○	○	○	5 crackers or 2 handfuls	○	○	○
Popcorn	○	○	○	○	○	○	○	○	○	4 handfuls or 2 cups	○	○	○
Peanut butter, peanuts, other nuts and seeds	○	○	○	○	○	○	○	○	○	2 tablespoons or 1 handful	○	○	○
Butter, margarine or oil, on bread or tortillas	○	○	○	○	○	○	○	○	○	2 pats or 2 teaspoons	○	○	○
Mayonnaise and mayonnaise type spreads, on sandwiches and in salads	○	○	○	○	○	○	○	○	○	2 tablespoons	○	○	○

TYPE OF FOOD	HOW OFTEN DID YOU EAT THE FOOD (Mark one)									AMOUNT			
	Never or less than once per month	1 per month	2-3 per month	1 per week	2 per week	3-4 per week	5-6 per week	1 per day	2+ per day	Medium Serving Size	Your Serving Size S	M	L
BREAKFAST FOODS													
Cold cereal	○	○	○	○	○	○	○	○	○	1 cup or 1 medium bowl	○	○	○
Cooked cereals and grits	○	○	○	○	○	○	○	○	○	1 cup or 1 medium bowl	○	○	○
Margarine or butter added to cooked cereal or grits	○	○	○	○	○	○	○	○	○	2 pats or 2 teaspoons	○	○	○
Milk on cereal (cold and cooked)	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Pancakes and waffles	○	○	○	○	○	○	○	○	○	2 pancakes or 1 medium waffle	○	○	○
Eggs	○	○	○	○	○	○	○	○	○	2 eggs	○	○	○
Bacon, breakfast sausage, and scrapple	○	○	○	○	○	○	○	○	○	3 strips or 2 links or 1 slice	○	○	○
DAIRY PRODUCTS													
Low-fat cottage cheese	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Cottage cheese and ricotta cheese	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Non-fat cheeses. Include cheese added to foods and in cooking	○	○	○	○	○	○	○	○	○	2 slices or 1/4 cup shredded	○	○	○
Part-skim or reduced fat cheeses, such as Mexican-type cheeses or mozzarella. Include cheese added to foods and in cooking	○	○	○	○	○	○	○	○	○	2 slices or 1/4 cup shredded	○	○	○
All other cheeses, such as cheddar, Swiss, or cream cheese. Include cheese added to foods and in cooking	○	○	○	○	○	○	○	○	○	2 slices or 1/4 cup shredded	○	○	○
Non-fat yogurt (not frozen)	○	○	○	○	○	○	○	○	○	1 cup	○	○	○
All other yogurt (not frozen)	○	○	○	○	○	○	○	○	○	1 cup	○	○	○
SWEETS													
Ice cream	○	○	○	○	○	○	○	○	○	1 scoop or 3/4 cup	○	○	○
Pudding, custard, and flan	○	○	○	○	○	○	○	○	○	3/4 cup	○	○	○
Low-fat or non-fat frozen desserts, such as frozen yogurt, sherbet, ice milk, and low-fat milkshakes	○	○	○	○	○	○	○	○	○	1 scoop or 3/4 cup	○	○	○

PLEASE MAKE NO MARKS IN THIS AREA

708571

TYPE OF FOOD	HOW OFTEN DID YOU EAT THE FOOD (Mark one)									AMOUNT			
	Never or less than once per month	1 per month	2-3 per month	1 per week	2 per week	3-4 per week	5-6 per week	1 per day	2+ per day	Medium Serving Size	Your Serving Size S	M	L
Doughnuts, cakes, pastries, Pop-Tarts®, and pan dulce	○	○	○	○	○	○	○	○	○	1 piece	○	○	○
Cookies	○	○	○	○	○	○	○	○	○	3 small or 1 large	○	○	○
Pumpkin and sweet potato pie	○	○	○	○	○	○	○	○	○	1 medium slice	○	○	○
All other pies, fried pastries, pastelitos and fruit empanadas	○	○	○	○	○	○	○	○	○	1 medium slice or 1 piece	○	○	○
Chocolate candy and candy bars	○	○	○	○	○	○	○	○	○	1 small bar or 1 ounce	○	○	○
Hard candy, jam, jelly, honey, or syrup	○	○	○	○	○	○	○	○	○	3 pieces or 1 tablespoon	○	○	○

BEVERAGES (Please note that the frequency headings are different.) →	HOW OFTEN DID YOU EAT THE FOOD (Mark one)									AMOUNT			
	Never or less than once per month	1-3 per month	1 per week	2-4 per week	5-6 per week	1 per day	2-3 per day	4-5 per day	6+ per day	Medium Serving Size	Your Serving Size S	M	L
Milk, all types (including canned and soy) not on cereal	○	○	○	○	○	○	○	○	○	8 ounce glass	○	○	○
Regular soft drinks (not diet)	○	○	○	○	○	○	○	○	○	12 ounces or 1 can	○	○	○
Beer	○	○	○	○	○	○	○	○	○	12 ounce can or bottle	○	○	○
Wine	○	○	○	○	○	○	○	○	○	1 medium glass (6 ounces)	○	○	○
Liquor	○	○	○	○	○	○	○	○	○	1 shot (1 1/2 ounces)	○	○	○
Coffee or tea (all types)	○	○	○	○	○	○	○	○	○	8 ounce cup	○	○	○
Milk, cream, or creamer in coffee or tea	○	○	○	○	○	○	○	○	○	1 tablespoon	○	○	○
Sugar in coffee or tea and on cereal	○	○	○	○	○	○	○	○	○	2 teaspoons	○	○	○

SUMMARY QUESTIONS (please note that the frequency headings are different.)	Less than one per week	1-2 per week	3-4 per week	5-6 per week	1 per day	2 per day	3 per day	4 per day	5+ per day
How often did you use fat to deep-fry, pan fry, or sauté? Count all fat such as margarine, oil, bacon drippings, or lard.	○	○	○	○	○	○	○	○	○
How often did you add fat when cooking beans, rice, vegetables, and potatoes? Count all fat such as margarine, oil, bacon drippings, or lard.	○	○	○	○	○	○	○	○	○
How often did you eat a serving of vegetables? Do not count salad, potatoes or dried beans or peas.	○	○	○	○	○	○	○	○	○
How often did you eat a serving of fruit? Do not count juices.	○	○	○	○	○	○	○	○	○

THANK YOU! ***Please take a moment to fill in any questions you may have skipped.***

PLEASE MAKE NO MARKS IN THIS AREA

708571

Printed in U.S.A. R11758-PFI-5432

NAME _____ DATE _____

SEX: Male (M) Female (F)

IDENTIFICATION

Below is a list of words that describe feelings people have. Please read each one carefully. Then fill in ONE circle under the answer to the right which best describes HOW YOU HAVE BEEN FEELING DURING THE PAST WEEK INCLUDING TODAY.

The numbers refer to these phrases.

0 = Not at all
1 = A little
2 = Moderately
3 = Quite a bit
4 = Extremely

Col (C) O.P. (O)

	NOT AT ALL	A LITTLE	MODERATELY	QUITE A BIT	EXTREMELY
1. Friendly	0	1	2	3	4
2. Tense	0	1	2	3	4
3. Angry	0	1	2	3	4
4. Worn out	0	1	2	3	4
5. Unhappy	0	1	2	3	4
6. Clear-headed	0	1	2	3	4
7. Lively	0	1	2	3	4
8. Confused	0	1	2	3	4
9. Sorry for things done	0	1	2	3	4
10. Shaky	0	1	2	3	4
11. Listless	0	1	2	3	4
12. Peeved	0	1	2	3	4
13. Considerate	0	1	2	3	4
14. Sad	0	1	2	3	4
15. Active	0	1	2	3	4
16. On edge	0	1	2	3	4
17. Grouchy	0	1	2	3	4
18. Blue	0	1	2	3	4
19. Energetic	0	1	2	3	4
20. Panicky	0	1	2	3	4
21. Hopeless	0	1	2	3	4
22. Relaxed	0	1	2	3	4
23. Unworthy	0	1	2	3	4
24. Spiteful	0	1	2	3	4
25. Sympathetic	0	1	2	3	4
26. Uneasy	0	1	2	3	4
27. Restless	0	1	2	3	4
28. Unable to concentrate	0	1	2	3	4
29. Fatigued	0	1	2	3	4
30. Helpful	0	1	2	3	4
31. Annoyed	0	1	2	3	4
32. Discouraged	0	1	2	3	4
33. Resentful	0	1	2	3	4
34. Nervous	0	1	2	3	4
35. Lonely	0	1	2	3	4
36. Miserable	0	1	2	3	4
37. Muddled	0	1	2	3	4
38. Cheerful	0	1	2	3	4
39. Bitter	0	1	2	3	4
40. Exhausted	0	1	2	3	4
41. Anxious	0	1	2	3	4
42. Ready to fight	0	1	2	3	4
43. Good natured	0	1	2	3	4
44. Gloomy	0	1	2	3	4
45. Desperate	0	1	2	3	4
46. Sluggish	0	1	2	3	4
47. Rebellious	0	1	2	3	4
48. Helpless	0	1	2	3	4
49. Weary	0	1	2	3	4
50. Bewildered	0	1	2	3	4
51. Alert	0	1	2	3	4
52. Deceived	0	1	2	3	4
53. Furious	0	1	2	3	4
54. Efficient	0	1	2	3	4
55. Trusting	0	1	2	3	4
56. Full of pep	0	1	2	3	4
57. Bad-tempered	0	1	2	3	4
58. Worthless	0	1	2	3	4
59. Forgetful	0	1	2	3	4
60. Carefree	0	1	2	3	4
61. Terrified	0	1	2	3	4
62. Guilty	0	1	2	3	4
63. Vigorous	0	1	2	3	4
64. Uncertain about things	0	1	2	3	4
65. Bushed	0	1	2	3	4

MAKE SURE YOU HAVE ANSWERED EVERY ITEM.

EdITS POM 021

SELECT Trial – INITIAL QUESTIONNAIRE

Distribution Number: _____
Participant's Number: _____
Clinic: _____

*You will only need to fill out this INITIAL QUESTIONNAIRE once. Please fill out all questions completely and accurately. All information will be kept **strictly confidential** and used for research purposes only.*

Today's date ..... _____

A) PARTICIPANT'S INFORMATION * * * * * * * *

Name: _____
(Last) (First) (M.I.)
Date of Birth: ..... *DOB:* _____
Social Security Number: ..... *SSN:* _____
Mailing Address:

Street or PO Box: _____

City _____ State: _____ Zip Code: _____

☐ *Check here and complete **section** I if you have more than one address.*

Approximately **how much time** does it take to get from your home to the blood draw site? ..... _____ HOURS _____ MINUTES

Home Phone:( ) _____ Work Phone: ( ) _____

Best time to contact you ..... time____ AM PM ANYTIME
Best place to contact you..... HOME / WORK

B) MEDICAL RECORDS RELEASE * * * * * * * *

I give permission to the *SELECT Trial* to obtain copies of my medical records from my medical care providers for the duration of the study. I understand that this information will be kept strictly confidential and used for research purposes only.

_____ _____
Signature Today's Date

C) PERSONAL HISTORY * * * * * * * *

What is your current **age**? ..... _____ YEARS

What is your race?..... CAUCASIAN ____
AFRICAN AMERICAN ____
HISPANIC ____
ASIAN ____
AMERICAN INDIAN ____
OTHER _____

What is your height?..... _____FEET/INCHES

What is your weight? ..... _____LBS.

What is your current marital status?..... *(Circle one)* SINGLE MARRIED DIVORCED WIDOWED

What is the highest grade you have completed in **school**? *(Circle the highest grade completed)*

NONE	1	2	3	4	5	6	7	8	9	10	11	12		13	14	15	16		17	18+

D) CONTACT PERSON * * * * * * * *

*Please supply the name and address of a **contact person** or **next of kin** that is NOT living with you.*

Name of contact person:_____

Street Address:_____

City, State, ZIP:_____

Phone:_____

Relationship:_____

E) OCCUPATIONAL INFORMATION * * * * * * * *

What is your current or most recent **occupation**? ....._____

What **type of work** did you spend the most years doing? _____

What are/were the **main duties** at this workplace? .._____

Are you currently retired? ..... YES NO

Are you currently, or have you ever served in the military service? YES NO

F) TOBACCO USE * * * * * * * *

Use the following chart to record your tobacco usage. Follow the indentations to answer questions relating to the previous question.

Cigarettes		
Do you **smoke cigarettes currently**?		YES NO
	If YES, how **many cigarettes** do you smoke per day?	#/DAY
	How **old** were you when you **first started** smoking?	AGE=
	If NO, have you **ever smoked cigarettes**?	YES NO
	If YES, how many cigarettes did you **smoke per day**?	#/DAY
	How old were you when you **first started** smoking	AGE=
	How old were you when you **last stopped** smoking?	AGE=
	If you have ever smoked cigarettes, but do not fit into any of the above categories, please explain:	
Have you **ever lived with a smoker**?		YES NO
	If YES, **as a child** (ages 0-18), how many **years** did you live with a smoker	#YEARS
	If YES, **as an adult**, how many **years** did you live with a smoker?	#YEARS

Do you currently **smoke cigars**?		YES NO
	If YES, how many **years**?	YEARS=
	If NO, have you **ever smoked cigars**?	YES NO
Do you currently **smoke a pipe**?		YES NO
	If YES, how many **years**?	YEARS=
	If NO, have you **ever smoked a pipe**?	YES NO
Do you currently **chew tobacco**?		YES NO
	If YES, how many **years**?	YEARS=
	If NO, have you **ever chewed tobacco**?	YES NO

G) ALCOHOL USE * * * * * * * *

Use the following chart to record your alcohol usage. Follow the indentations to answer questions relating to the previous question.

Do you currently **drink BEER, WINE, or LIQUOR**			YES NO
	If YES, **how often** do you drink alcohol?		__ LESS THAN ONE/WEEK __ ONE DAY PER WEEK __ 2-3 DAYS PER WEEK __ 3-7 DAYS PER WEEK
		When you drink alcohol, how many drinks do you usually have each time?	DRINKS=
	If NO, have you **ever** consumed alcohol?		YES NO
		How many days in the week did you drink alcohol?	#/WEEK
		How many drinks did you usually have each day?	#/DAY
		How many years did you drink alcohol?	YEARS=

H) GENERAL HEALTH * * * * * * * *

Do you currently or have you ever had problems with the following:

Nails	YES NO
Unexplained hair loss	YES NO
Persistent garlic odor on your breath (excluding meals)	YES NO
Fatigue	YES NO
Nausea	YES NO

If you answered YES to any of the above questions, please list date(s) and describe the problem(s):

Have you had any of the following:

If you answer YES to any of the following questions, please LIST THEM ON THE ILLNESS DOCUMENTATION FORM on the PROCEDURES and SURGERIES FORM.

Cancers (other than skin & prostate)	YES NO
Hospitalizations	YES NO
Cancer screenings	YES NO
Other Illnesses	YES NO

I. SECOND ADDRESS:

Street Address: ....._____

City, State, ZIP: ....._____

Phone: ....._____

I am at this address from ____/____ (mm/dd) to ____/____ (mm/dd)

J) ILLNESS DOCUMENTATION

* * * * * * * *

Check any of the following illnesses and medical conditions you may have had in the last five years.

[__] Check here if you have had NO ILLNESSES in the past FIVE (5) years.

ILLNESS	When?	PHYSICIAN	HOSPITAL
EXAMPLE: High Blood Pressure	*6/25/97*	*Dr. Albert Smith*	*Rose Medical Center*
[__] Cancer: What Type?			
[__] Glaucoma			
[__] Cataracts			
[__] Colon Polyps			
[__] Heart Problems: What Kind?			
[__] Hospitalizations: Why?			
[__] Other:			

K) PROSTATE BIOPSIES DOCUMENTATION * * * * * * * *

Please list all past prostate biopsies.

BIOPSY DATE	PHYSICIAN	HOSPITAL/CLINIC	BIOPSY RESULT
EXAMPLE: 8-25-99	Dr. Albert Smith	Trinity Memorial Hospital	Negative

L) PRESCRIPTION MEDICATION DOCUMENTATION FORM * * * * * * * *

Please list all current prescription medications.

[ ] Check here if you take NO PRESCRIPTION MEDICATIONS currently.

MEDICATION	DOSAGE	HOW OFTEN	REASON	START DATE	STOP DATE	PHYSICIAN	SPECIALTY
EXAMPLE: Penicillin	*250 mg*	*3 a day*	*bronchitis*	*2/1/97*	*2/13/97*	*Dr. Albert Smith*	*Internist*

M) VITAMIN, MINERAL, HERBAL, AND NON-PRESCRIPTION * * * * * * * *

Please list all current vitamin or mineral supplements, herbal remedies and NON-prescription medications.

[ ] Check here if taking NO VITAMIN, MINERAL, HERBAL OR NON-PRESCRIPTION MEDICATIONS.

MEDICATION/ SUPPLEMENT	DOSAGE	HOW OFTEN	REASON	START DATE	STOP DATE
EXAMPLE: Iron	325 mg	1 a day	anemia	2/1/97	2/13/97

N) PHYSICIAN INFORMATION FORM

* * * * * * * *

*Please list **all** of your current doctors below:*

Physician _____

Specialty _____

Facility/Hospital _____

Address _____

City, State, Zip Code _____

Phone _____ Fax _____

Physician _____

Specialty _____

Facility/Hospital _____

Address _____

City, State, Zip Code _____

Phone _____ Fax _____

Physician _____

Specialty _____

Facility/Hospital _____

Address _____

City, State, Zip Code _____

Phone _____ Fax _____

Physician _____

Specialty _____

Facility/Hospital _____

Address _____

City, State, Zip Code _____

Phone _____ Fax _____

Physician _____ Specialty _____ Facility/Hospital _____ Address _____ City, State, Zip Code _____ Phone _____ Fax _____	Physician _____ Specialty _____ Facility/Hospital _____ Address _____ City, State, Zip Code _____ Phone _____ Fax _____
Physician _____ Specialty _____ Facility/Hospital _____ Address _____ City, State, Zip Code _____ Phone _____ Fax _____	Physician _____ Specialty _____ Facility/Hospital _____ Address _____ City, State, Zip Code _____ Phone _____ Fax _____

Select Study – FOLLOW-UP STUDY-VISIT

Name: _____
Distribution Number/Visit Number: _____/_____
Participant's Number: _____
Clinic: _____

This is the FOLLOW-UP STUDY VISIT QUESTIONNAIRE. Please fill out all questions completely and accurately. All information will be kept strictly confidential and used for research purposes only.

- Today's date.....*Date*_____

- Since my last visit, I missed taking a pill: *(circle one)*
  - ____1. NEVER (LESS THAN ONCE A MONTH)
  - ____2. ABOUT ONCE A MONTH
  - ____3. ABOUT ONCE A WEEK
  - ____4. MORE THAN ONCE A WEEK
  - ____5. STOPPED THEN RESTARTED TAKING THE PILLS
  - ____6. STOPPED AND DID NOT RESTART

- *If you stopped taking the pills, please answer the following:*
  Date I **stopped** taking the pills.....*Date*_____

  Date I **restarted** taking the pills .....*Date*_____

Please describe the reason for stopping pills:

	Do you have any new problems with:	*Choose:*	*Enter the date:*
1	persistent garlic odor on your breath? (not related to meals)	YES NO	
2	persistent hair loss?	YES NO	
3	persistent nails splitting?	YES NO	
4	persistent fatigue?	YES NO	
5	persistent nausea?	YES NO	

MEDICAL RECORDS RELEASE

* * * * *

I give permission to the *Select Study* project to obtain copies of my medical records from my medical care providers for the duration of the study. I understand that this information will be kept strictly confidential and used for research purposes only.

_____ _____
Signature *Today's Date*

Illness Documentation

*[__] Check here if you have had **NO NEW ILLNESSES** since your last study visit.*

ILLNESS	WHEN?	PHYSICIAN	HOSPITAL
EXAMPLE: High Blood Pressure	*6/25/97*	*Dr. Albert Smith*	*Rose Medical Center*
[__] **Cancer:** What Type?			
[__] **Glaucoma**			
[__] **Cataracts**			
[__] **Colon Polyps**			
[__] **Heart Problems:** What Kind?			
[__] **Hospitalizations:** Why?			
[__] **Other:**			

Procedures and Surgeries Documentation

*[__] Check here if you have had **NO PROCEDURES OR SURGERIES** since your last study visit.*

PROCEDURE/SURGERY	DATE	PHYSICIAN	HOSPITAL
EXAMPLE: Colonoscopy	11/16/97	Dr. Albert Smith	Rose Medical Center

Prescription Medication Documentation

*[__] Check here if you have had **NO NEW PRESCRIPTION MEDICATIONS** or **CHANGES** since your last study visit.*

PRESCRIPTION MEDICATION	DOSAGE	HOW OFTEN	REASON	START DATE	STOP DATE	PHYSICIAN
EXAMPLE: Penicillin	250 mg	3 a day	bronchitis	2/1/97	2/13/97	Dr. Albert Smith

Select Study– FOLLOWUP STUDY-VISIT

List any vitamin or mineral supplements, herbal remedies or non-prescription drugs

*[__] Check here if you have had **no change** or **no new items** since your last study visit*

Are you taking any multivitamin supplements? YES No (circle one)

If yes, how much Selenium does it contain? _____mcg *[__] Check if vitamin contains **no Selenium***

SUPPLEMENT	DOSAGE	HOW OFTEN	REASON	START DATE	STOP DATE
EXAMPLE: *Iron*	*325 mg*	*1 a day*	*anemia*	*2/1/97*	*2/13/97*

Comments?

Select Study

UROLOGICAL SYMPTOMS QUESTIONNAIRE

Name: _____

Distribution Number/VisitNumber: _____ / _____

Participant ID Number: _____

Clinic: _____

Today'sDate [ ][ ] / [ ][ ] / [ ][ ][ ][ ]

These questions on the UROLOGICAL SYMPTOMS QUESTIONNAIRE will help monitor your health condition relating to the prostate and the use of supplements.

USE A PENCIL OR BLACK PEN. MAKE A CHECK IN FRONT OF THE APPROPRIATE RESPONSE

1	How has your appetite been?	_ 1-GOOD _ 2-FAIR _ 3-POOR
2	What is your current weight?	LBS: _____
3	Have you experienced any of these weight changes?	_ 1-WEIGHT LOSS _ 2-WEIGHT GAIN _ 3-NO CHANGE _____ # OF POUNDS
4	Are you trying to lose weight?	_ YES _ NO

Since your LAST STUDY VISIT

Make only one Choice

5	Do you have any new **aches** or **pain**?	_ YES _ NO WHERE? _____
6	Have you experienced any **numbness** or **tingling**?	_ YES _ NO WHERE? _____
7	Have you experienced any **weakness** in your **arms**?	_ YES _ NO

UROLOGICAL SYMPTOMS QUESTIONNAIRE

Make only one Choice

8	Have you experienced any **weakness** in your **legs**?	_ YES _ NO
9	How many times do you usually **get up at night** to urinate? (from the time you go to bed until the time you get up in the morning.)	_ 0-NONE _ 1-ONE TIME _ 2-TWO TIMES _ 3-THREE TIMES _ 4-FOUR TIMES _ 5-FIVE TIMES _ 6-SIX OR MORE TIMES
10	How often have you had a sensation of not completely emptying your bladder after urination?	_ 1-NOT AT ALL _ 2-LESS THAN 1 IN 5 TIMES _ 3-LESS THAN HALF THE TIME _ 4-ABOUT HALF THE TIME _ 5-MORE THAN HALF _ 6-ALMOST ALWAYS
11	How many times have you had to urinate again less than two hours after your last urination?	_ 1-NOT AT ALL _ 2-LESS THAN 1 IN 5 TIMES _ 3-LESS THAN HALF THE TIME _ 4-ABOUT HALF THE TIME _ 5-MORE THAN HALF _ 6-ALMOST ALWAYS
12	How often have you found that you stop and start again several times while urinating?	_ 1-NOT AT ALL _ 2-LESS THAN 1 IN 5 TIMES _ 3-LESS THAN HALF THE TIME _ 4-ABOUT HALF THE TIME _ 5-MORE THAN HALF _ 6-ALMOST ALWAYS
13	How often have you found it difficult to postpone urination?	_ 1-NOT AT ALL _ 2-LESS THAN 1 IN 5 TIMES _ 3-LESS THAN HALF THE TIME _ 4-ABOUT HALF THE TIME _ 5-MORE THAN HALF _ 6-ALMOST ALWAYS

(Over Please)

UROLOGICAL SYMPTOMS QUESTIONNAIRE

Make only one Choice

14	How often have you had a weak urinary stream?	_ 1-NOT AT ALL _ 2-LESS THAN 1 IN 5 TIMES _ 3-LESS THAN HALF THE TIME _ 4-ABOUT HALF THE TIME _ 5-MORE THAN HALF _ 6-ALMOST ALWAYS
15	How often have you had to push or strain to begin urination?	_ 1-NOT AT ALL _ 2-LESS THAN 1 IN 5 TIMES _ 3-LESS THAN HALF THE TIME _ 4-ABOUT HALF THE TIME _ 5-MORE THAN HALF _ 6-ALMOST ALWAYS
16	Have you seen any blood in your urine?	_ 1-INITIALLY _ 2-FINISHING _ 3-TOTAL _ 4-CLOTS _ 5-NONE
17	How do you rate your stream?	_ 1-GOOD _ 2-FAIR _ 3-WEAK _ 4-STEADY _ 5-INTERMITTENT _ 6-DOUBLE
18	Have you noticed any stress incontinence? *(leakage of urine when sneezing, coughing or laughing)*	_ YES _ NO
19	If **YES**, please rate your incontinence	_ 1-STABLE _ 2-IMPROVED _ 3-WORSE _____ # OF PADS/24 HOURS

(Over Please)

5	Have you experienced any of these? (Choose all that apply)	_ NAUSEA _ VOMITING _ FEVER _ CHILLS _ NO SYMPTOMS

Appointment Information

24	My **LAST** urology appointment was:	DATE: ___/___/____
25	My **NEXT** urology appointment is:	DATE: ___/___/____ _ NO APPOINTMENT SCHEDULED
26	My **NEXT** blood draw appointment is:	DATE: ___/___/____ _ NO APPOINTMENT SCHEDULED

Comments?

SELECT/NBT STUDY LABORATORY FROM (visit #1)

Distribution Number_____
Patient Number_____
Clinic_____
Interviewer_____

Patient Name:_____

Was blood drawn? YES NO

If yes, please complete the information in this box. If no, please choose a reason from the list at the bottom of the page.

Please affix sample label here: _____

Date: _____ **Time of blood draw:**_____**am/pm**

Time of last meal: _____**am/pm**

Weight: _____

Please Complete: Date of Next Visit_____

****

In the last week, have you experienced the following?
(These may effect your PSA level)

1.	**Have you been treated for a urinary or prostate infection?**	**YES NO**
2.	**Have you used a urinary catheter?**	**YES NO**
3.	**Had any type of sexual activity that resulted in in ejaculation?**	**YES NO**

If blood **could not be drawn**, please indicate the reason why by circling one of the following items:

1. Unable to find an adequate vein
2. Unable to draw enough blood
3. Refused
4. Withdrawn from study
5. Other- Reason _____

Appendix II: Procedures Manual

Table of Contents

SELECT TRIAL
CLINIC PROTOCOL FOR SITES WITHIN TUCSON

1) **Initial Contact at Urology Visit:**
   a) Patient is referred to your urology clinic for an examination due to a high PSA level or other indication of potential prostate cancer.
   b) Patient has a repeat PSA and DRE and other appropriate examination.
   c) If patient is a surgical candidate, present patient with study brochure.

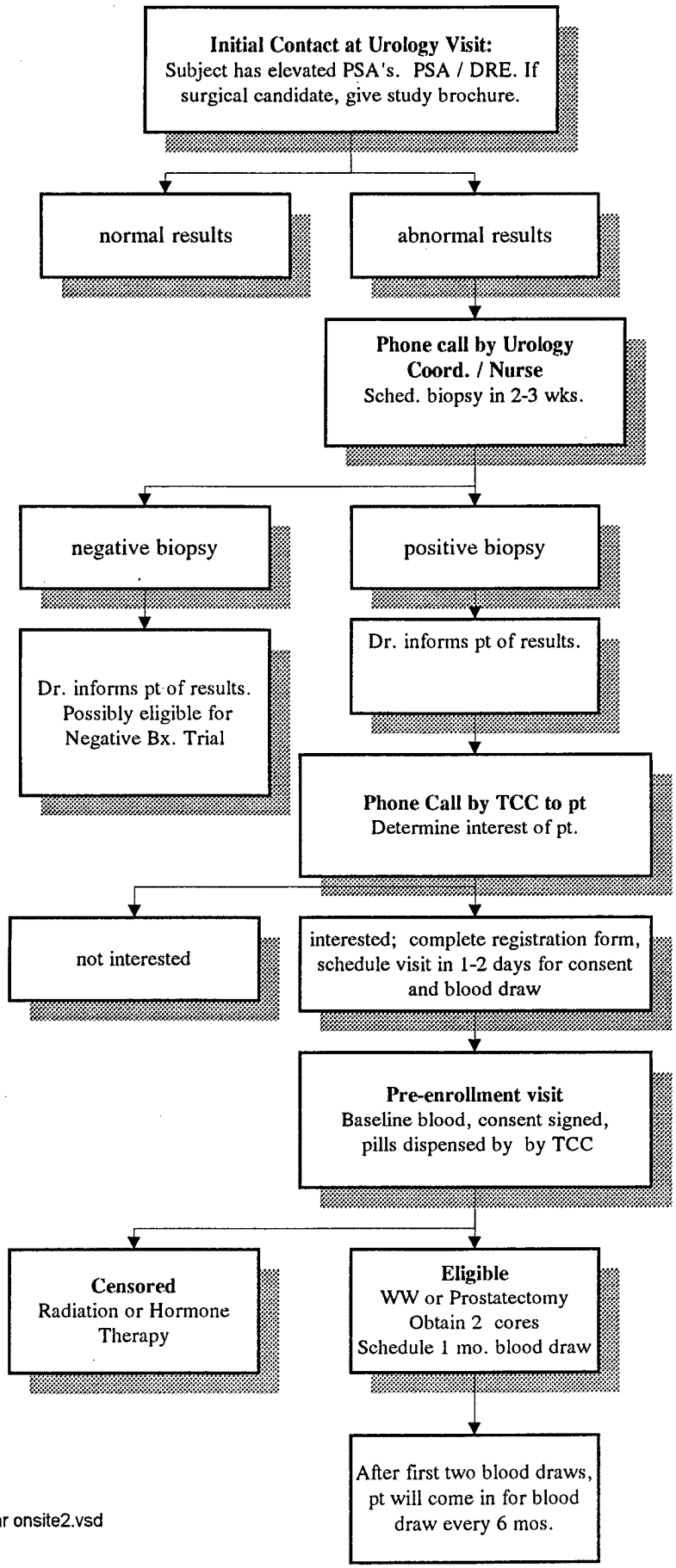
2) **If patient has a biopsy positive for prostate cancer:**
   a) Inform patient of biopsy results
   b) Determine patient interest in Select study
   c) If patient wishes to participate, complete registration form and fax to the Tucson Coordinating Center (TCC).
   d) TCC will then schedule the visit to occur within a day or two, if possible, completing the consent form and blood draw at that visit.
   e) Pills are dispensed from TCC, pills will be directly administered or federal expressed and participant will be given more information about the study.

3) **If patient has a biopsy negative for prostate cancer:**
   a) Your office informs patient of results.
   b) Patient may be eligible for NBT.

6) **Treatment choice for PCa**
   a) If participant chooses to have a **prostatectomy or observation (Watchful Waiting)**, he will continue to be followed by the TCC.
   b) If participant chooses any treatment other than those listed in "a", he will be censored.

7) **Further follow-up for participant**
   a) TCC office will schedule participant for second blood draw one month after prostatectomy.
   b) Participant will continue with semi-annual blood draws at the TCC.
   c) TCC will mail and monitor baseline, food frequency, and follow-up questionnaires.

SELECT TRIAL
Flow Diagram (within Tucson)



P: SELECT study/misc/SELECT chr onsite2.vsd

SELECT TRIAL
CLINIC PROTOCOL FOR SITES OUTSIDE OF TUCSON

1) **Initial Contact at Urology Visit:**
   a) Patient is referred to your urology clinic for an examination due to a high PSA level or other indication of potential prostate cancer.
   b) Patient has a repeat PSA and DRE and other appropriate examination.
   c) If patient is a surgical candidate, present patient with study brochure

2) **If patient has a biopsy positive for prostate cancer:**
   a) Inform patient of biopsy results
   b) Determine patient interest in Select study
   c) If patient wishes to participate, complete registration form and fax to the Tucson Coordinating Center (TCC).
   d) Schedule visit to occur within a day or two, if possible, then complete consent form at the visit and draw blood.

   e) If pills are dispensed at clinic, clinic will hold a randomized block of pills and dispense pills at time of blood draw and informed consent. *TCC will mail more information about the study.*

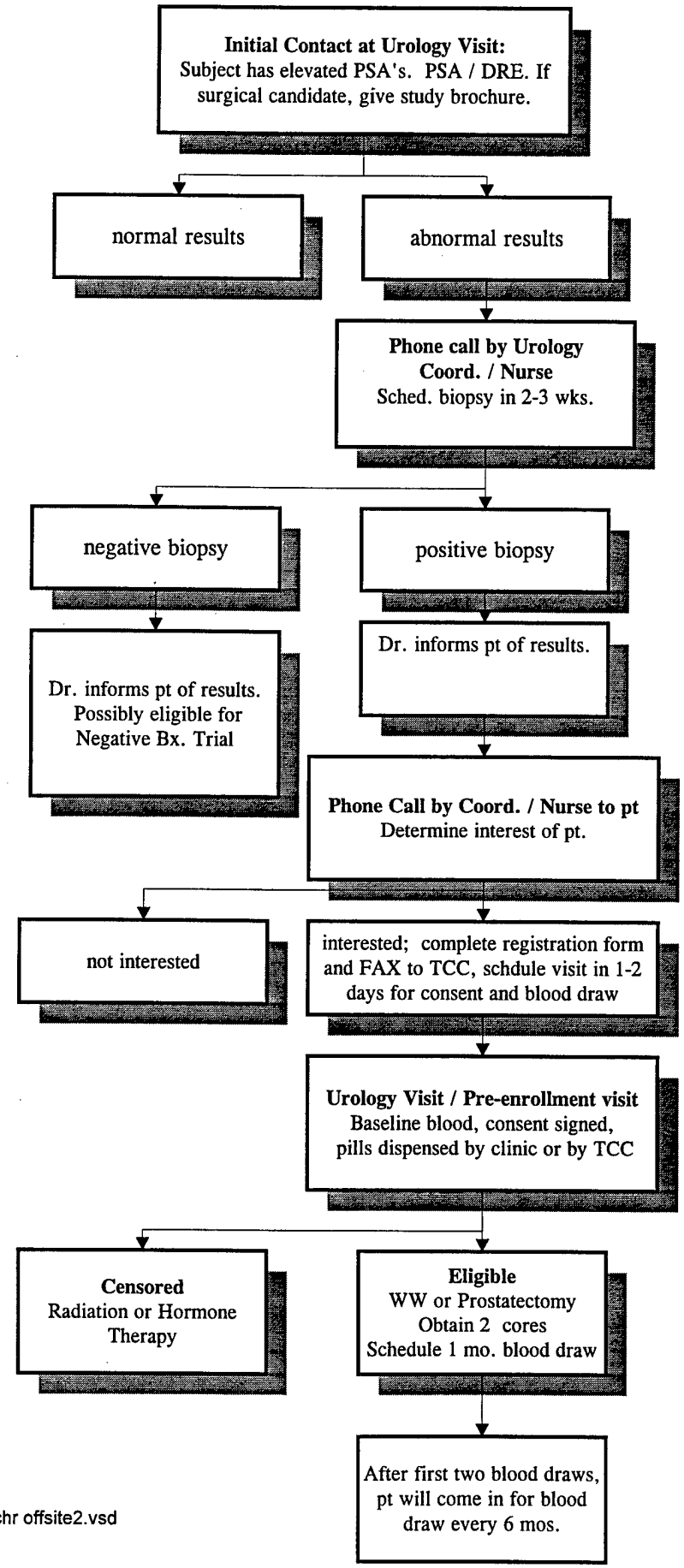
   f) If pills are dispensed from TCC, pills will be federal expressed and be given more information about the study.

3) **If patient has a biopsy negative for prostate cancer:**
   a) Your office informs patient of results.
   b) Patient may be eligible for NBT.

6) **Treatment choice for PCa**
   a) If participant chooses to have a **prostatectomy or observation (Watchful Waiting)**, he will continue to be followed by the TCC.
   b) If participant chooses any treatment other than those listed in "a", he will be censored.

7) **Further follow-up for participant**
   a) Schedule participant for second blood draw one month after prostatectomy.
   b) Participant will continue with semi-annual blood draws.
   c) TCC will mail and monitor baseline, food frequency, and follow-up questionnaires.

SELECT TRIAL
Flow Diagram (outside of Tucson)



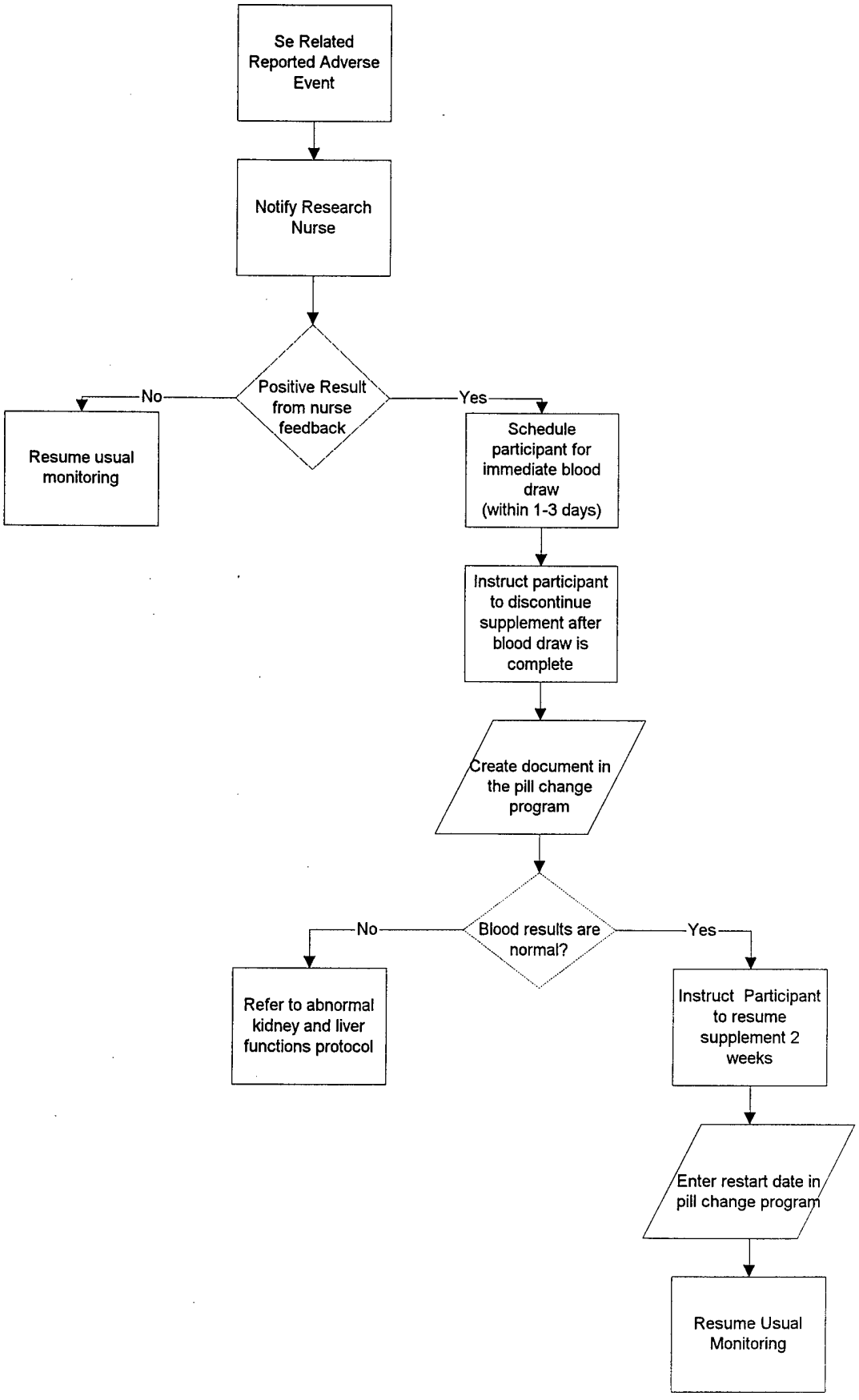
P: SELECT study/misc/SELECT chr offsite2.vsd

Dates to Remember

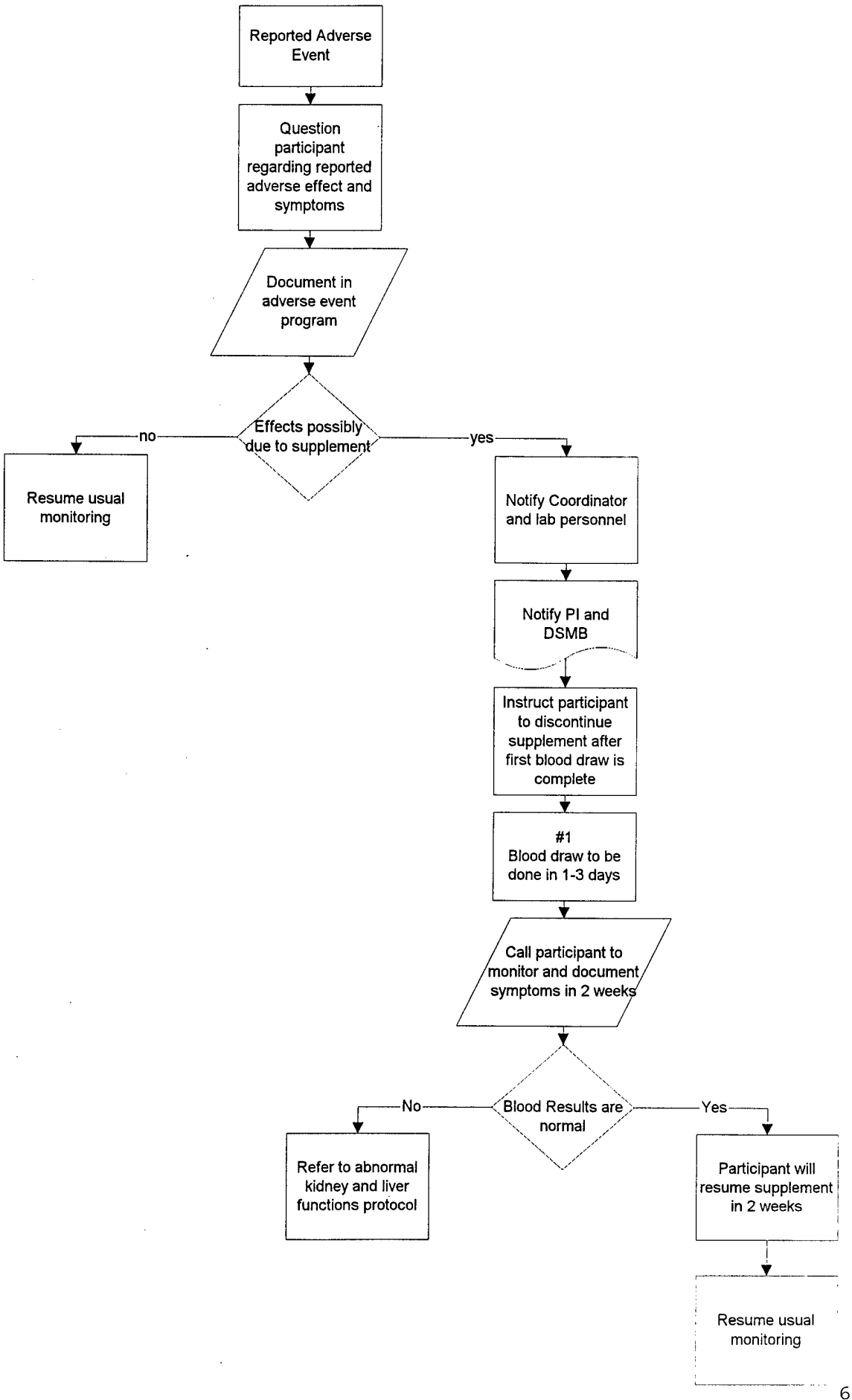
Recruitment Date:	Date on the Registration form
Randomization Date:	Date participant is randomized in the computer program
First Pill Date:	Date first study pill taken (derived from pill postcard)

P:\SeLECT study\Misc\Dates to Remember.doc

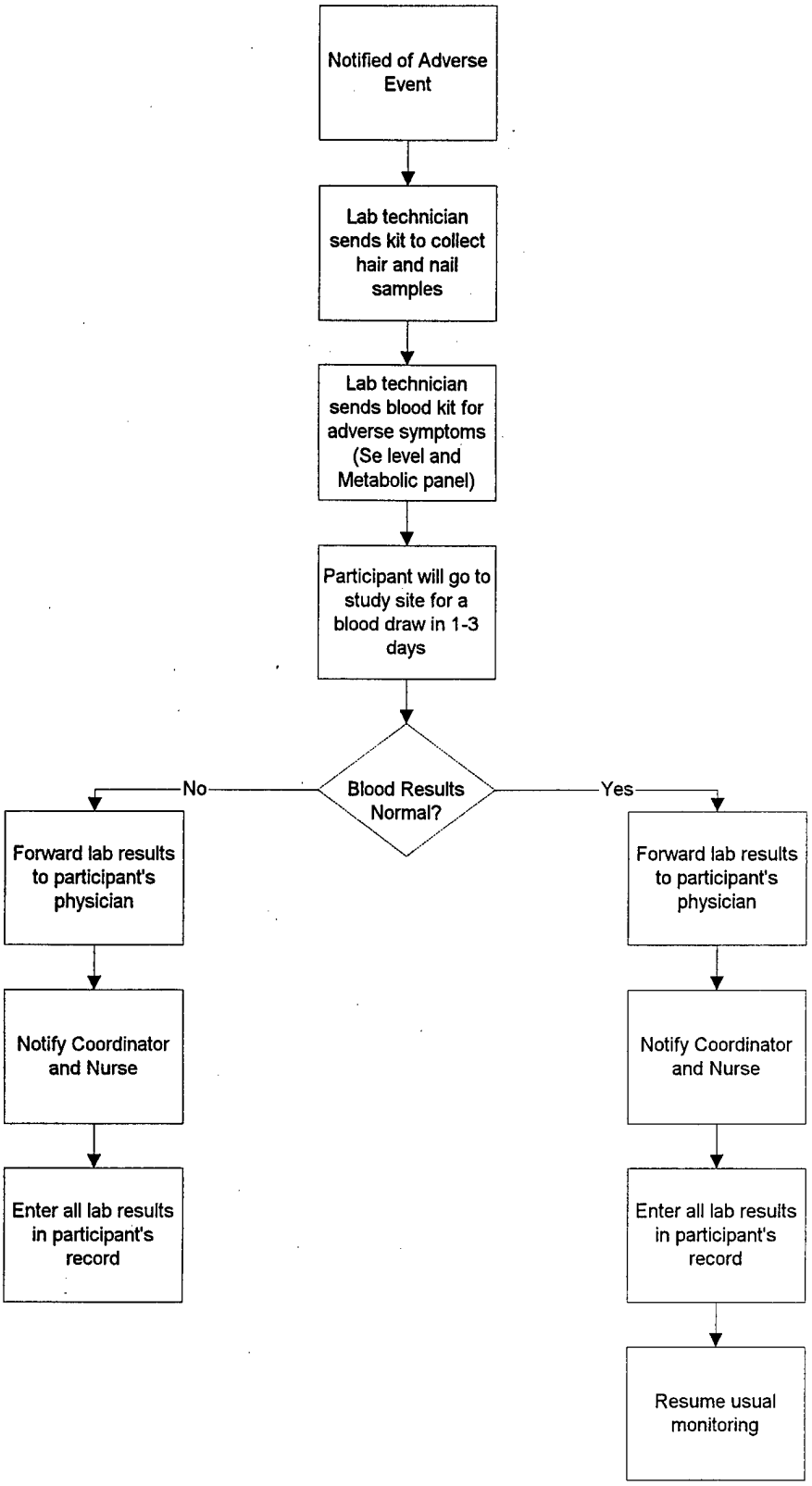
Coordinator
Adverse Effect Protocol



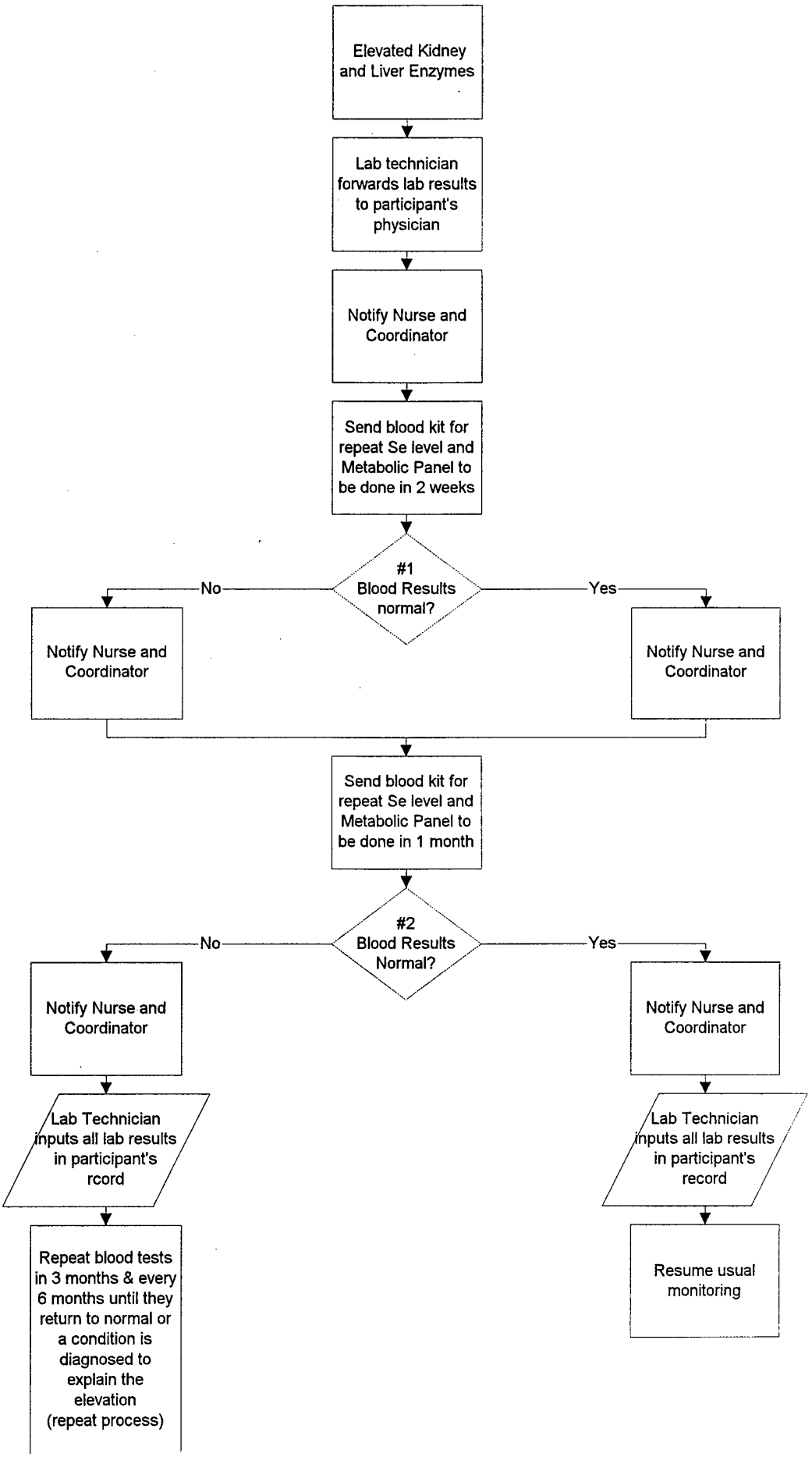
Nurse
Adverse Effect Protocol



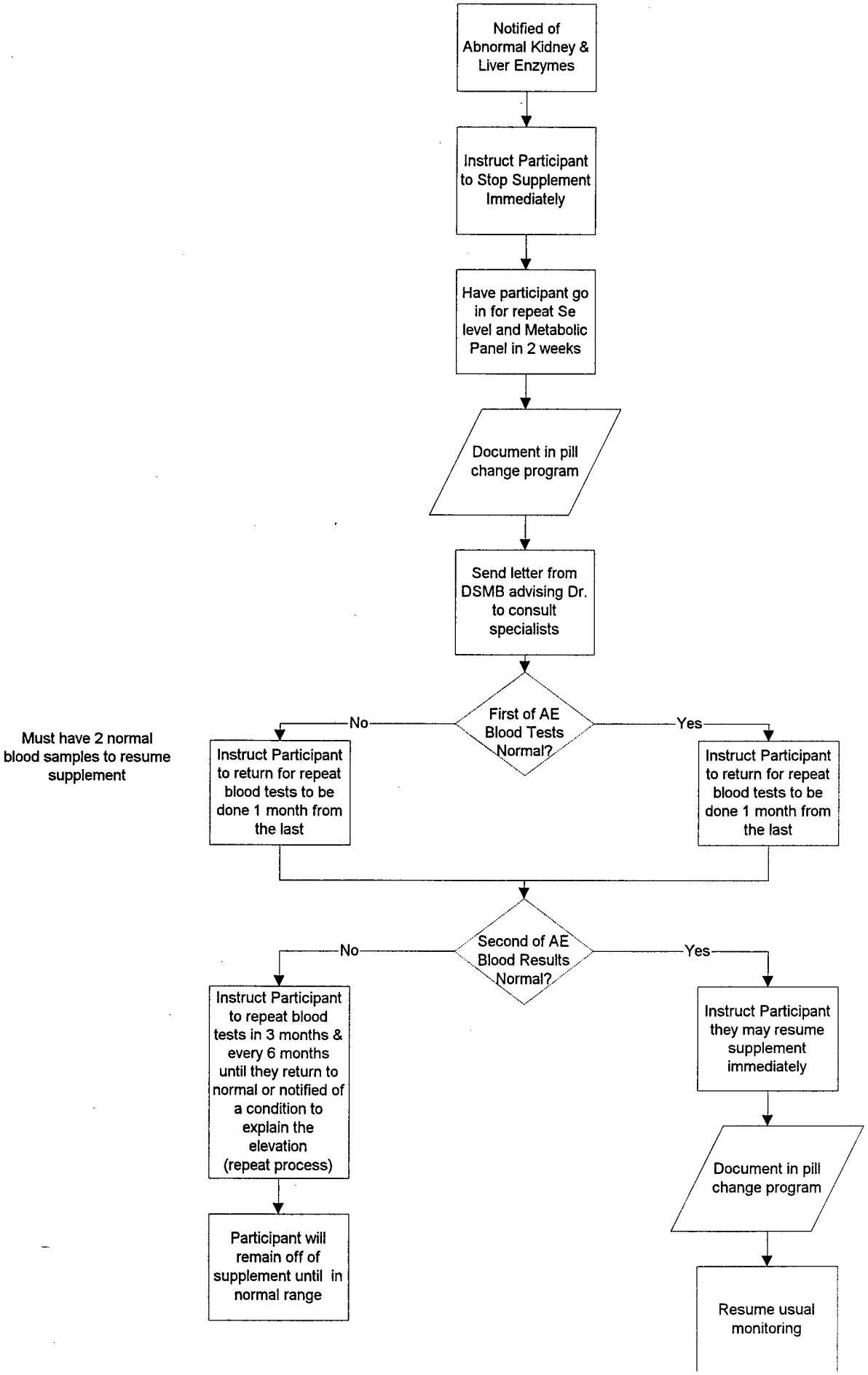
Laboratory
Adverse Effects Protocol



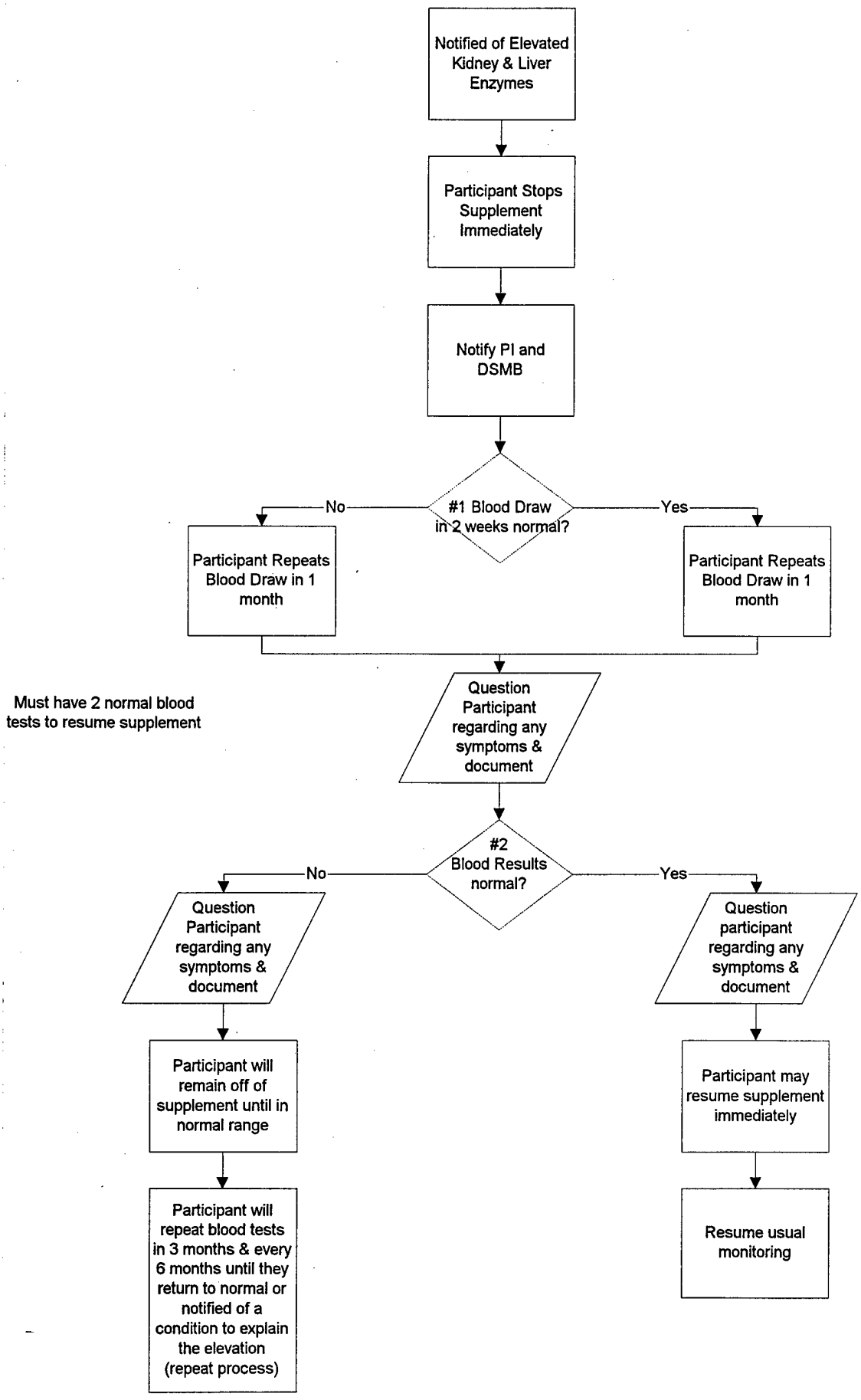
Laboratory
Elevated Kidney and Liver Enzymes Protocol
(2 X nl)



Coordinator Protocol
Elevated Kidney & Liver Enzymes
(2 X nl)



Nurse Protocol
Elevated Kidney & Liver Enzymes
(2 X nl)



PILL INFORMATION

Pill Material Supplied By:

Cypress Systems, Inc.
5150 N. 6th St.
Suite 156
PO Box 25729
Fresno, CA 93729

Phone number: (209) 229-9122
Fax number: (209) 225-9007

Pill Formulation Done By:

Pharma Nord
Administration:
Sadelmagervej 30-32
DK-7100 Vejle
Denmark

Production:
Tinglykke 4-6
DK-6500 Vojens
Denmark

Phone number 75 85 74 00
Fax number: 75 85 74 74

SELECT
Computer Entry Instructions- New Patient Registration

1. Receive fax
2. Go to the SELECT program and click on add patient button.
   This will open to the main screen and then you enter patient name, SS# and DOB on the top half of the screen.
3. Go the address tab and enter the information. (May have to enter status as 'recruited' in order to gain access to address tab) Note: what you put in for address may change when you get the initial questionnaire. If the participant has more than one address, put start and stop dates to the left of each address)
4. Go to the Registration tab and enter the recruited by (person in the Dr.'s office), the recruited date (upper right-hand corner of the registration form), and the initials of the coordinator assigned to this participant. Check off any boxes for documentation you may have (could be coming in the mail). "Recruited" should appear in the status box. If not, select recruited from the drop down box.
5. To mail participant the information packet
   a. Go to the distribution tab and select "info packet" from the drop down box. Under item category put 1 under number of mailing labels column (do not put date in date distributed box, it will think you already sent it and will not let you print. It will appear automatically after printing job in complete).
   b. Go to print labels button and highlight the patient's name. (Click on the row)
   c. Click on the print mail label button and the label will appear.
      If it looks correct and you have labels in the printer then click on the little printer in the toolbar on top.
6. Items in the Information Packet
   Thank you sheet - on lavender
   Study Summary sheet - on yellow
   Patient information sheet (2 pages) - on pink
   Folder for patient to keep stuff in (when ordered)
   These items should be found in the Protocol Notebook and in the P drive, SeLECT folder in <u>forms.</u>
7. If patient is interested in participating, fax back registration log to the clinic with the patient ID#.

P:\SeLECT Study\Protocols\New patient\new participant initial entry.doc

SELECT
Computer Entry Instructions-Patient Randomization protocol

1. If not in already, click on icon to open SELECT program, pt table will open automatically. Highlight participant's name and click on 'edit patient' button.

2. Click on the 'Registration' tab. Then, hit the 'Randomize' button in the middle of the screen. 'Randomized' should appear in the status box. If not, select randomized from the drop down box.

3. To mail participant study pills and questionnaire packet.

   A. Click on the 'distribution' tab. Click on the pull down menu for the last empty window table cell at the bottom of the 'item category' column. From this pull-down menu, choose 'Study Pills'. The program will automatically bring up a window asking you how many bottles you wish to distribute, it should default on '1', then click ok. There should now be a '1' in the column for the quantity of pills. If you haven't generated a label for your questionnaire mailing envelope, put a '2' in the quantity column for mailing – one label for the pill shipment, one label for questionnaires envelope. In the 'expect response' column put 'no' for the study pills.

   B. Click on the pill button to see what type of pills this person has been assigned to get– it will be a single letter designation and will also be listed on the pill label. Close the window.

   C. Hit the 'print label' button. A table will come up with several pt.'s names– hilight the participant's name, and then hit the 'print pill label' button. The label will be displayed on the screen. Make sure you have a label sheet loaded in the printer (it takes (Avery 5164, 3 1/3 " x 4" labels), then click on the print icon (or press Ctrl + P, and then 'enter'). Next, print the mail labels. Hit 'print label' button, hilight participant name, click on the 'print mail label' button, and click on the print icon.

   D. Go get participant's pills in the pill room. Grab a box on the shelf with the letter that corresponds to the one-letter designation for the type of pills the participant had been assigned after randomization. That letter is on the pill label. For the intial shipment of study pills, send only one blister flat of pills. Once you grab the pills, make sure you remember who it is for because there is nothing on the pills to designate what pill group it belongs to.

   E. Grab a yellow pill information sheet titled: 'SELECT—Participant Pill Instructions'. Place the pills in a ziploc baggie with the pills intructions and a pill postcard (with the participant's id# and distribution # for the pills written on it). Place the pill label on the outside of the baggie.Get a mailing box. Put the participant's pills in this box. Please put two layers of cellophane tape on both sides of the box to make sure it is sealed properly. Put mailing label on top.

SELECT
FORMS ENTRY PROTOCOL

Open SELECT. This can be done either with the **SELECT icon** or by going to **M:\SeLect\SSentry.mdb** and opening the program. Microsoft Access must be installed on the user's computer to be able to access these programs.

Highlight the name of the desired patient. This activates the **[Edit Patient]** button, which allows entry of all patient questionnaires. **Click the [Edit Patient] button**.

Verify the Patient ID: Located in the top left-hand corner of the **Patient file** entry screen, and the right hand corner of the form to be entered. **This field is not entered by the user.** It is a unique, sequential number assigned to the patient by the computer. It represents the order in which the patient was randomized into the study. After a patient is randomized and entered into the Patient's table, the program then arranges the table in alphabetical order to facilitate data entry.

Generally, if you have any **blank fields** as you are entering information, use the following **protocol**:

Date questions:
If the question is supposed to be skipped, as part of the instructions on the questionnaire, leave it blank (this includes if the participant was not supposed to fill it out and put something there).

If the question is supposed to be answered, but the participant left it blank, leave it blank. This marks the information as missing and obtainable.

If the date will not ever be found (such as chronic diseases), then enter 11/11/1111. This means that the data is unobtainable.

Alphanumeric and numeric questions:
If the question is supposed to be skipped, as part of the instructions on the questionnaire, leave it blank (this includes if the participant was not supposed to fill it out and put something there).

If the question is supposed to be answered, but the participant left it blank, leave it blank. This marks the information as missing and obtainable.

If the information is unobtainable (because the patient refused to answer, they said they 'didn't know', or the question is not applicable for some reason), first choose 'missing' if it is a choice in the data entry program. If 'missing' is not a choice, then enter –9.

Patient General Information Screen: Verify each of these fields from the form being entered and update, if necessary. The fields are arranged in three columns progressing from left to right, top to bottom. Each field can be accessed by either using the **[Tab]** button, or by clicking the mouse on the desired field.

First Column:

Last name:

First name:

Middle:

Title: Choose **Mr.**, **Dr.**, or **Rev.** from the drop down menu (or Ms. or Mrs. for the truly confused)

Second Column:

SS Num:

Birth date:

Chart Num: Patient's chart number at clinic, if known.

Off-site: Patient's clinic location. This should <u>always</u> be checked, all clinics are considered off-site now.

Third Column:

Status: This field reflects the current participant status. Choose from the following ONLY if a Status has changed:

For <u>all</u> initial questionnaires, 1st urology and follow-up questionnaires, and (possibly) 2nd urology questionnaire entry (any questionnaires <u>before</u> randomization: Use these fields for any questionnaires returned BEFORE study pills are received:

-Recruited: Status before Initial questionnaire entry should be this.
-Dropped out BEFORE randomization: ONLY used for those participants who dropped out prior to receiving study pills. (During recruitment and run-in period**). If this option occurs, proceed to Reason.**
-Ineligible to participate

For Urology and Follow-up Questionnaires <u>after</u> randomization: Choose one of the following:

-Randomized-Active
-Randomized-Temporarily Inactive:
-Dropped out AFTER randomization: If choosing this option, proceed to **Reason.**

Reason: This text box is only available if status = dropped out. Choose the option that best describes the participant's reason for dropping out of the study.

-(blank) Currently Active
-(other) Personal Reasons
-Deceased
-Lost to follow-up
-Mentally unfit
-No time for study-too busy
-Patient not responsive
-Pills too large
-Potential side effects
-Spouse or family interference
-Taking too many supplements
-Taking too many medications
-Tired of Being in study
-Too ill to continue in study
-Not eligible
-

The remainder of the patient's file can be accessed by clicking the appropriate file tabs on the bottom portion of the screen. **For questionnaire entry, Click the [Questionnaires] file tab**.
Entering Questionnaires.

Highlight the appropriate questionnaire form, either **Initial, Follow-Up**, or **Urology**. This activates the Open Questionnaire button. **Click the [Open Questionnaire] button**.

Initial Questionnaire:

Verify the Distribution Number: Located on the right at the top of both the entry screen and the form to be entered. The Distribution Number is assigned to each form and logged into the patient's file before it is mailed to the study patient. It is linked to all information entered from a given form into the patient's data file and will be used as the source of the information.

Verify the Patient ID & Clinic: Located in the right hand corner of the form to be entered.
Verify Patient Name:
Questionnaire date: This is **Today's date** on the form, located in the top right hand corner of the questionnaire. Enter all dates numerically as MMDDYY, the program will automatically add date slashes and correct for Y2K.
SS Num: Social Security number, enter/update, if necessary
Birth Date: MMDDYY

Address: This is the first file to be updated or entered from the Initial Questionnaire form. Address information is located in the upper half of the first page of the Initial Questionnaire. The format of the fields on the entry screen progresses across the screen, from left to right. Verify that all information in the address file matches that of the Initial Questionnaire form and update, if necessary.

1-Address Form Entry:

The first two fields are date fields, which are ONLY used for patients with two or more addresses (i.e., summer homes). These fields are found in **Section I** of the Initial Questionnaire form. They indicate where correspondence should be mailed in order to reach the patient at different times of the year. Enter the dates the patient expects to reside at each address.

Starting: Use MMYY as the format of this field.
Ending: Use MMYY for the format of this field.

The remaining fields are found on the first page of the Initial Questionnaire.

Address: Use this field for the major portion of the patient's address.
Address: Use only if any portion of the address did not fit in the field above.
City:
State: Type the two-letter state abbreviation, or choose the correct state from the pull down menu.
Zip: five-digit numeric
Home Phone: See next field
Work Phone: Enter the area code and seven-digit telephone number, without parentheses or dashes. The program will automatically add these to the fields.

The following three fields do not appear on the Address entry screen. They can be accessed using the horizontal scroll bar located in the bottom right hand corner of the screen.

Best Time: Enter the numeric time, if applicable, and/or **AM** or **PM**.
Best Place: Use the pull down menu and choose either **Home** or **Work**.
Travel Minutes: enter the time it takes for the participant to get from that address to the clinic.

[Tab] through all of the fields to enter the record, increment the record number and to create the next empty record for future use.
Note: Do not update an address before determining whether it is a new address or a second address. Repeat the Address Form Entry with each additional address from **Section I,** entering one address per line. The program will automatically update the number of records in the Address file and create an empty record at the end of the file for future entry. **However, the user should verify that he/she is at the end of the address file before entering any additional addresses**. The empty record at the end of each file is proceeded by the symbol **[*]**. This can also be ascertained by checking the record scroll bar located in the bottom left hand corner of the screen.

The Address form entry is now complete. **[Click] on the [History] tab.**

2-History Form Entry:

Med Rel Form Date: This is the date of the Medical Records Release Form, which is found in **Section B, Medical Records Release**, at the bottom of the first page of the Initial Questionnaire.

The remaining seven fields of the **History** file are found on the second page of the Initial Questionnaire form in **Section C, Personal History**. The user can **[Tab]** through the entire form and progress through the fields in the same order as that of the questionnaire.

Personal History:

Current Age:
Race: use the pull-down menu and choose the participant's response from the following options:

-Caucasian
-African American
-Hispanic
-Asian
-Native American
-Other

Height Feet: Enter only the whole number for the patient's height in feet (no inches here!)
Height Inches: Enter the number of inches recorded for the patient's height.
Weight lbs.: Enter a whole number.
Marital Status: use the pull-down menu and choose the participant's response from the following options:

-Single
-Married
-Divorced
-Widowed

Highest Grade: Highest grade completed in school. Enter the number, or use the drop down menu to choose the participant's response.

The History form entry is now complete. **[Click] on the [Contact/Occupation] tab.**

3-Contact Person or Next of Kin/Occupational History Entry:

Contact Person: This information is found in **Section D, Contact Person** on the bottom half of page two of the Initial Questionnaire. Note: if the contact person is living in the same household as the patient, call and get a contact person at another address and phone number.

Contact Name: Enter the Name of the Contact Person or Next of Kin, with Salutation, First and Last Name (Middle Name and/or Initial is optional).
Street: Enter full street address. If the first line of the address is a business name, enter it here and enter the street address in the field below.
Street: Use this field for the full street address only if the previous field was used for a business name.
City:
State: Choose from the drop down menu or type the two-letter abbreviation for the state
Zip Code: Include the nine digit extended zip, with the dash, if known
Phone: Include area code and all dashes, the program does not add them in this screen.
Relationship: Of contact person to patient, if known

Occupation Information: Located in **Section E, Occupational Information**, on the second page of the Initial Questionnaire.

Current Occupation:
Longest Occupation:
Main Duties: If there are several, list one on each line.
Currently Retired: Choose (1)Yes, (0)No or (9)Missing from drop down menu.
Former Military: Choose (1)Yes, (0)No or (9)Missing from drop down menu.

The Contact/Occupation form entry is now complete. **[Click] on the [Tobacco Use] file tab**.

3-Tobacco Use: This information is found in **Section F, Tobacco Use**, on the third page of the Initial Questionnaire. The easiest method of entering this page is to use the **[Tab]** button to move from field to field, rather than pointing and clicking with the mouse.

Note: The easiest method of entering the **[YES/NO]** information queries is to type one of these three responses:

1-for Yes
0 -for No
9 -for Missing

The program will choose the correct response from the pull down menus and the full answer will appear in the field without any additional typing. The user also has the option of choosing the correct response from the pull down menu, or manually typing in a YES/NO answer. **These entry options also apply to the Alcohol Use file.**

Tobacco Use Form Entry:

Current Smoker: YES/NO
Cigarettes per day: (NOTE: if they put a range, choose the **highest** number- for example, if they say 5-7, enter 7. A pack has 20 cigarettes)
Age started:

Former Smoker: YES/NO
Cigarettes per day:
Age started:
Age stopped:

Cigarette smoking description: This is a text box used to describe any smoking habits that are not adequately defined by the previous questions (i.e., 1 cigarette every other day). Use this box to fully describe any unique conditions.

Lived with smoker: YES/NO
Years as adult:
Years as child:

Smoke cigars: YES/NO
Years:
Ever: YES/NO

Smoke a pipe: YES/NO
Years:
Ever: YES/NO

Chew tobacco: YES/NO
Years:
Ever: YES/NO

Note: The program does not automatically default to the next [YES/NO] question in response to a [NO] answer. If a user enters a [NO] answer, he/she must manually tab through the information fields that correspond to a [YES] answer until the next [YES/NO] field is encountered. **These conditions also apply to the Alcohol Use file.**

If any [YES/NO] fields are blank, use the **[9-Missing]** option. If any of the numeric fields in response to a [YES] answer are blank, leave the field blank. **In either event, or if any answer is unclear or incorrect, call the participant as soon as possible to complete the questionnaire.**

The Tobacco Use Section is now complete. **[Click] on the [Alcohol Use] file tab**.

4-Alcohol Use: This information is found in **Section G, Alcohol Use**, on the fourth page of the Initial Questionnaire form. The entry format is identical to that of the Tobacco Use Section. **Please refer to the Tobacco Use Entry Section for a detailed description of methods for entering the YES/NO question options.**

Alcohol Use Form Entry:

Current drinker: YES/NO
Days per week: This question refers to how many days a week the patient drinks alcohol.
Choose one of the following numbers, which will pull up the correct response from the pull down menu:
(NOTE: if they put a range**,** choose the **highest** number- for example, if they say 2 to 3, enter 3**)**

1-Less than one day/week
2-One day/week
3-2-3 days/week
4-3-7 days/week
9-Missing

Drinks/Day: **(NOTE:** if they put a range**,** choose the **highest** number- for example, if they say 5-7, enter 7**)**

Former Drinker: YES/NO
Days per week:
Drinks per day:
Years:

If any answer is blank, unclear or incorrect call the participant as soon as possible to complete the questionnaire.

The Alcohol Use File is now complete. **[Click] on the [Health] file tab.**
6-Health Information: This information is found in **Section H, General Health**, on the fourth page of the Initial Questionnaire. All fields, with the exception of the **Description** text box, follow the same YES/NO entry format of the Tobacco and Alcohol Use sections. **Please refer to the Tobacco Use Entry Section for a detailed description of methods for entering the YES/NO question options.**

Health Information Form Entry:

Nail Splitting: YES/NO
Hair Loss: YES/NO
Garlic Breath: YES/NO

Note: If the patient answers **[YES]** to any of the previous three questions, inform the Project Nurse immediately. These are the beginning symptoms of selenium toxicity and must be monitored

Fatigue: YES/NO
Nausea: YES/NO
Description: This text box is only used if any of the previous five questions were answered **[YES].** The information should be entered using this format:

Problem-date started (MM/DD/YY)

Use one line per problem.
Cancers: YES/NO
Hospitalizations: YES/NO
Cancer Screenings: YES/NO
Other Illnesses: YES/NO

Note: If the patient answered **[YES]** to any of the four previous questions, make sure that each event is also listed on **the Illness Documentation form.**

If any answer is blank, unclear or incorrect call the participant as soon as possible to complete the questionnaire.

The Health Information entry is now complete. **[Click] on the [Illnesses+] file tab.**

7-Illnesses+: The Illness Documentation Form is found in **Section J, Illness Documentation,** on the sixth page of the Initial Questionnaire. The format of the fields progresses across the page, from left to right. The order of the fields on the Illness Documentation Form match those of the Illness and Procedures file, with the exception of the **Ill. Class field**, which is completed by the nurses after the Initial Questionnaire is entered. Enter one illness per line, making sure each entry is as complete as possible.

Illness Documentation Form Entry:

"Check here if No Illnesses or Medical Procedures in the last 5 years": If this box is checked on the questionnaire, and there are no illnesses reported on the rest of the form, **[Click]** on the check box to enter a check into the Illnesses and Procedures screen. **Proceed to the [Medications+] File Tab.**

If Illnesses are reported:

Verify the Distribution Number
Verify the Illness Record Number: This can be ascertained by checking the record status on the record scroll bar, located in the bottom left-hand corner of the screen. **Note:** The first illness record on the Initial Questionnaire Form should be record #1!!

Illness or proc: Use text to describe the illness event fully. If applicable, use standardized abbreviations for events, such as HBP for high blood pressure.
Ill. Class: Tab through this field, the nurses will complete this.
Start: Enter as MMDDYY, the computer will add the date slashes and correct for Y2K.

If the start date is unknown (i.e., History of..), enter 11/11/1111

Stop: Enter as MMDDYY, the computer will add the date slashes and correct for Y2K.

If the illness is chronic or the end date is unknown, enter 11/11/1111.

For either the Start or Start Date:

If the month and year are known and the day is unknown, use MM15YY

If only the year is known use 0701YY

Doctor: Use the pull down menu to find the physician associated with the event, or type in his/her name. Highlight the physician's name and press [Enter]. The **Doctor, Specialty** and **Clinic or Hosp** fields will be automatically entered when the doctor is choosen.
Specialty: Will update automatically when the **Doctor** field is entered.
Clinic or Hosp: Will update automatically when the **Doctor** field is entered.
If the patient only lists a hospital or clinic and no doctor:

Enter: the **Department of Medical Records** option, from the **Doctors** pull down menu.

Attach: the appropriate Clinic or Hospital from the **Clinics** pull down menu. (This circuitous method is in response to inefficient programming.)

Note: This method should also be used if the medical records for the event will be obtained from the hospital and not the physician, or if the patient sees several doctors at the same facility.

In the event that <u>both</u> the Physician and Clinic are not located in the Doctors or Clinic Tables, please see Appendix [XX] Adding Doctors/Clinics.

The following five fields in the Illness or Procedure file are not shown on the Questionnaire form. They also do not appear on the Illness and Procedures entry screen but can be accessed using the horizontal scroll bar in the lower right hand corner of the screen.

Reported: This is the date of the Questionnaire, entered MMDDYY.
Source: This should automatically be updated with the **[Questionnaire]** option in the pull down menu. If, for some reason it does not update, choose **[Questionnaire]** from the pull down menu.

The remaining three fields, **Doc Requ.**, **Doc Compl.**, and **Doc Recv**. are not completed by the user during questionnaire entry. **However, [Tab] through all of the fields to enter the record, increment the record number and to create the next empty record for future use.**

Repeat the Illness entry process with each illness reported by the patient. The program will automatically update the number of records in the Illnesses and Procedures file and create an empty record at the end of the file for future entry. **However, the user should always verify that he/she is at the end of the file before entering any additional records**. The empty record at the end of each file is proceeded by the symbol **[*]**. The end of the file can also be ascertained by checking the status on the **record scroll bar**, located in the bottom left-hand corner of the screen. Make sure that the record scroll bar is at the end of the file. If not, **[Click]** the **[▸*]** button on the right side of the bar to create a new record.

As the patient's illness file grows, illness records can be accessed using the vertical scroll bar located on the right side of the Illness or Procedure screen.

Note: If a surgery is listed, a corresponding illness should either exist already in the illness table, or be added along with the surgery report. For instance, if a cataract surgery is reported, an illness record of "Cataracts " should be added to the illness table if one is not yet in place. **Enter all Surgeries and/or Procedures reported.**

If any answer is blank, unclear or incorrect, call the participant as soon as possible to complete the questionnaire.

The Illnesses+ section is now complete. **[Click] on the [Medications+] file tab.**

8-Medications+: The Medication Documentation Form is found in **Section K, Prescription Medication Documentation Form**, on the seventh page of the Initial Questionnaire form. The format of the fields progresses across the page, from left to right. Enter one medication per line, making sure each entry is as complete as possible.

Medication Documentation Form Entry:

"Check here if you take NO MEDICATIONS currently": If this box is checked on the questionnaire, and there are no Medications reported on the rest of the form, **[Click]** on the check box to enter a check into the Medications and Supplements Screen. **Proceed to the Vitamin, Mineral, Herbal, and Non-Prescription Form entry.**

If Medications are reported:

Verify the Distribution Number
Verify the Medication Record Number: This can be ascertained by checking the status on the record scroll bar, located in the bottom left-hand corner of the screen. **Note**: The first Medication record entered from the Initial Questionnaire should be #1!!

Medication: Type in the name of the medication. Appropriate standard abbreviations are also acceptable if known, such as EES for erythromycin.
Dosage: Numeric dosage with the abbreviated weight/unit designation
How often: Use standard abbreviations, if known. (i.e., QD for once a day)
Reason: If known.

Refer to the **Illness Documentation Form Entry** for a complete description on the entry of the following four fields.

Start Date: Identical to the Illness Documentation Form Entry
Stop Date: Identical to the Illness Documentation Form Entry
Doctor: Identical to the Illness Documentation Form Entry
Specialty: Identical to the Illness Documentation Form Entry

The remaining two fields do not appear on the Questionnaire form. They also do not appear on the Medications and Supplements entry screen but can be accessed using the horizontal scroll bar in the lower right hand corner of the screen.

Source: This should automatically be updated with the "**Questionnaire**" option in the pull down menu. If, for some reason this field does not update, choose "**Questionnaire**" from the pull down menu.
Reported: This is the date of the Initial Questionnaire form, entered MMDDYY.

[Tab] through all of the fields to enter the record, increment the record number and to create the next empty record for future use.

Repeat the Medication entry process with each additional medication reported by the patient. With each new medication entry, the program will automatically update the number of records in the Medications and Supplements file and create an empty record at the end of the file for future entry. **However, the user should verify that he/she is at the end of the file before entering any additional records**. The empty record at the end of each file is proceeded by the symbol **[*]**. The end of file can also be ascertained by checking the status on the record scroll bar, located in the bottom left-hand corner of the screen. Make sure that the record scroll bar is at the end of the file. If not, **[Click]** the **[▸*]** button on the right side of the bar to create a new record.

As the patient's medications and supplement file expands, illness records can be accessed using the vertical scroll bar located on the right side of the Medications and Supplements screen.

Supplements: These are found on in **Section L, Vitamin, Mineral, Herbal and Non-Prescription Documentation Form**, on the eight page of the Initial Questionnaire form. Supplements are entered on the Medications and Supplements screen. Enter one supplement per line, making sure each entry is as complete as possible.

Supplements Form Entry:

"Check here if you take NO VITAMIN, MINERAL, HERBAL, OR NON-PRESCRIPTION MEDICATIONS currently": If this box is checked on the questionnaire, and there are no Supplements reported on the rest of the form, **[Click]** on the check box to enter a check into the Medications and Supplements Screen. **Proceed to the [Doctors] Form entry.**

If Supplements are reported:

Verify the Distribution Number
Verify the Supplement Record Number: The empty record at the end of each file is proceeded by the symbol **[*]**. This can also be ascertained by checking the record status on the record scroll bar, located in the bottom left-hand corner of the screen. Make sure that the record scroll bar is at the end of the file. If not, **[Click]** the **[▸*]** button on the record scroll bar to create a new supplement record.

Medication/Supplement: Type in the name of the supplement. Appropriate standard abbreviations are also acceptable if known, such as ASA for aspirin.
Dosage: Numeric dosage with the abbreviated weight/unit designation
How often: Use standard abbreviations, if known. (i.e., QD for once a day)
Reason: If known.
Start Date: Identical to the Illness Documentation Form Entry
Stop Date: Identical to the Illness Documentation Form Entry

The remaining four fields do not appear on the Questionnaire form. They also do not appear on the Medications and Supplements entry screen but can be accessed using the horizontal scroll bar in the lower right hand corner of the screen.

Doctor: Identical to the Illness Documentation Form Entry
Specialty: Identical to the Illness Documentation Form Entry
Source: This should automatically be updated with the **[Questionnaire]** option in the pull down menu. If, for some reason the field does not update, choose **[Questionnaire]** from the pull down menu.
Reported: This is the date of the Initial Questionnaire form, entered MMDDYY.

[Tab] through all of the fields to enter the record, increment the record number and to create the next empty record for future use.

Repeat the Supplement entry process with each additional supplement reported by the patient. With each new supplement entry, the program will automatically update the number of records held in the record scroll bar and will also add the next record entry line. **However, the user should verify that he/she is at the end of the file before entering any additional records**. The empty record at the end of each file is proceeded by the symbol **[*]**. The end of file can also be ascertained by checking the status on the record scroll bar, located in the bottom left-hand corner of the screen. Make sure that the record scroll bar is at the end of the file. If not, **[Click]** the **[▸*]** button on the right side of the bar to create a new record.

As the patient's medications and supplement file expands, illness records can be accessed using the vertical scroll bar located on the right side of the Medications and Supplements screen.

If any answer is blank, unclear or incorrect call the participant as soon as possible to complete the questionnaire.

The Medications and Supplements file is now complete. **[Click] on the [Doctors] File Tab.**

9-Doctors File: The Doctor's file is the section in which specific physicians, hospitals and clinics are attached to a patient. It is the **Patient's Doctor file**, a sub-file comprised of physicians, clinics and hospitals found in the Doctor's table and who are seen by a specific patient. As such, the Patient Doctor file is unique to each patient. **Adding a physician to a patient illness or medication record does not automatically add the doctor to the patient's Doctor file.** Every patient Doctor file must be created and/or updated manually.

Information about a patient's physicians comes from three sources: the **Illness and Procedures Documentation form**, the **Medications and Supplements Documentation form**, and **Section M, Physician Information form**. The format of the fields in the Doctor's file proceeds across the screen, from left to right.

Doctor Entry:
From the Illnesses and Procedures Documentation forms:

Check the Illnesses and Procedures Documentation forms: Create a patient doctor record for every physician, hospital and clinic found on the Illnesses and Procedures forms. Use one record line per practice.

Verify Distribution Number:
Verify the Doctor Record Number: The empty record at the end of each file is proceeded by the symbol **[*]**. This can also be ascertained by checking the record status on the record scroll bar, located in the bottom left-hand corner of the screen.

Doctor: Use the pull down menu to locate the patient's physician in the Doctor's Table. Highlight the doctor's name and press **[Enter]** to attach the physician to the patient.
Phone Number: Will automatically update when the **Doctor** field is choosen.
Clinic: Will automatically update when the **Doctor** field is choosen.

If the patient only lists a hospital or clinic and no doctor:
Enter: the **Department of Medical Records** option, from the **Doctors** pull down menu.
Attach: the appropriate Clinic or Hospital from the **Clinics** pull down menu. (This circuitous method is in response to inefficient programming.)

Note: This method should also be used if the medical records for the event will be obtained from the hospital and not the physician, or if the patient sees several doctors at the same facility.

The next two fields do not appear on the Illnesses and Procedures Documentation forms. The last field also does not appear on the Doctor's entry screen, but can be accessed using the horizontal scroll bar located in the bottom right hand corner of the screen.

Date first visit: If known, enter as MMDDYY.
Date last visit: If known, enter as MMDDYY.

[Tab] through all of the fields to enter the record, increment the record number and to create the next empty record for future use.

Repeat the Doctor entry process with each additional physician, hospital and/or clinic found on the Illnesses and Procedures Documentation forms. With each new doctor entry, the program will automatically update the number of records held in the record scroll bar and will also add the next record entry line. **However, the user should verify that he/she is at the end of the file before entering any additional records**. The empty record at the end of each file is proceeded by the symbol **[*]**. The end of file can also be ascertained by checking the status on the record scroll bar, located in the bottom left-hand corner of the screen. Make sure that the record scroll bar is at the end of the file. If not, **[Click]** the **[▸*]** button on the right side of the bar to create a new record.

From the Medications and Vitamin, Mineral, Herbal and Non-Prescription Documentation forms:

> **Check the Medications and Vitamin, Mineral, Herbal and Non-Prescription Documentation forms:** Create a patient doctor record for every physician, hospital and clinic found on these forms, **who has not already been attached from the Illnesses and Procedures forms.** Use one record line per practice. **The entry of these forms is identical to that of the Doctor entry from the Illnesses and Procedures forms.** Please refer to the Doctor's entry from the Illnesses and Procedures forms for complete entry instructions.

From the Physician Information form: The Physician Information form is found on the tenth page of the Initial Questionnaire form. The order of the fields in the Doctor's entry screen does not match that of the Physician Information form. **However, the entry of these forms remains identical to that of the Doctor entry from the Illnesses and Procedures forms**. Please refer to the Doctor's entry from the Illnesses and Procedures forms for complete entry instructions.

> **Check the Physician Information form:** Create a patient doctor record for every physician, hospital and clinic found on these forms, **who has not already been attached from the previous four forms.** Use one record line per practice.

Note: A physician, hospital or clinic must be added to the Doctor's table before they can be attached to a patient. **To add new physicians, hospitals and clinics, or edit existing records, Please refer to Appendix [XX], Adding/Editing Doctors and Clinics.**

The Initial Questionnaire Entry is now complete.

To Exit:

Close the Initial Questionnaire: [Click] the **[X]** in the top right hand corner of the window.

Close the Patient File: [Click] the **[X]** in the top right hand corner of the Patient File window. Use the horizontal scroll bar at the bottom of the screen to access the **[X].**

A Warning may pop up, stating that **frm.Patient** has been updated and should changes be saved. Choose **[YES].** (This means ECW is working!!!)

To Continue Working in SELECT: Choose **[Edit Patient]** from the SELECT Patient Menu to continue entering data on other patients.

To Close SELECT: [Click] the **[X]** in the top right hand corner of the window.

\\SELENIUM\PUB\SeLECT Study\Protocols\forms entry\Init_Quest_entry.doc

Follow-Up Study Questionnaire

The Follow-up questionnaire entry screen is broken up into four sections. The easiest method of entering this page is to use the **[Tab]** button to move from field to field, rather than pointing and clicking with the mouse. The screen will default on the last follow-up questionnaire entered.

Verify the Follow-Up Questionnaire Record Number: The user should always verify that he/she is at the end of the file before entering any additional records. The end of the file can be ascertained by checking the status on the **record scroll bar**, located in the bottom of the screen. Make sure that the record scroll bar is at the end of the file. If not, **[Click]** the **[▸*]** button on the right side of the bar to create a new record.

Verify the Patient's Name
Verify the Distribution Number: Located on the right at the top of both the entry screen and the form to be entered. The Distribution Number is assigned to each form by the study nurse and is logged into the patient's file before it is mailed to the study patient. It is linked to all information entered from a given form into the patient's data file and will be used as the source of the information. **Proceed to the Pills Section.**

Pills Section entry: This information is found on the first page of the Follow-up questionnaire.

> **Quest. Date:** Today's date on the follow-up questionnaire form. MMDDYY
> **Missed taking pills:** Type in the number of the following responses, or choose the correct response from the drop-down menu.
>
> > **1**-Never
> > **2**-About once a month
> > **3**-About once a week
> > **4**-More than once a week
> > **5**-Stopped then started (proceed to Stopped taking pills)
> > **6**-Stopped and did not restart (proceed to Stopped taking pills)
> > **9**-Missing
>
> **If the response to this question is 1-4 or 9, proceed to the Problems section.**
>
> **Stopped taking pills:** Enter the following three fields ONLY if participant answered 5 or 6 to the preceding question.
>
> > **Stop date:** MMDDYY
> > **Restart date:** MMDDYY (11/11/1111 if participant has not restarted pills)
> > **Reason for stopping pills:** Use this text field to fully describe the participant's reason for stopping the pills.

Note: Stopping pills also requires the user to complete a Pill Problem form, and a Status Change form. Also, the participant's status must be changed in the program through the Patient Information screen.

To change participant status:

Access Patient file: [Click] on the Patient window behind the Follow up Questionnaire window to access the participant's file.
Status: Use the drop down menu and choose one of the following:

-Randomized, Temporarily inactive: If participant is taking study pills and indicates that he has a temporary situation and will restart the pills when the problem is resolved.
-Dropped out BEFORE Randomization: If participant is not yet taking study pills
-Dropped out AFTER Randomization: If participant is taking study pills.

Reason: Choose the option that best describes the participant's reason for dropping out of the study.

-(blank) Currently Active
-(other) Personal Reasons
-Deceased
-Lost to follow-up
-Mentally unfit
-No time for study-too busy
-Patient not responsive
-Pills too large
-Potential side effects
-Spouse or family interference
-Taking too many supplements
-Taking too many medications
-Tired of Being in study
-Too ill to continue in study

If any answer is blank, unclear or incorrect call the participant as soon as possible to complete the questionnaire.

The Pill section is now complete. **[Click] on the Problems file tab.**

Problems: This information is found on the bottom half of the first page of the Follow-up questionnaire.

Note: The easiest method of entering the **[YES/NO]** information queries is to type one of these three responses:

1-for Yes
0 -for No
9 -for Missing

The program will choose the correct response from the pull down menus and the full answer will appear in the field without any additional typing. The user also has the option of choosing the correct response from the pull down menu, or manually typing in a YES/NO answer. Also, the program does not automatically default to the next [YES/NO] question in response to a [NO] answer. If a user enters a [NO] answer, he/she must manually tab through the information fields that correspond to a [YES] answer until the next [YES/NO] field is encountered.

Problems entry:

New garlic odor: [YES/NO]
Date: MMDDYY
New hair loss: [YES/NO]
Date: MMDDYY
New nail splitting: [YES/NO]
Date: MMDDYY

Note: If the patient answers **[YES]** to any of the previous three questions, inform the Project Nurse immediately. These are the beginning symptoms of selenium toxicity and must be monitored.

Problem description: Use this text field to fully describe any information the participant has provided in response to the above three questions.
MRF date: This field is found in the Medical Records Release section at the bottom of the first page of the questionnaire. Enter MMDDYY

If any answer is blank, unclear or incorrect call the participant as soon as possible to complete the questionnaire.

The Problems section is now complete. **[Click] on the Illnesses and Procedures file tab.**

Illnesses: The Illness Documentation Form is found on page two of the Follow-up questionnaire. The form entry is identical to that of the Illness Documentation form entry of the Initial Questionnaire. **Please refer to Section 7, Illnesses+, for a complete description of entering illnesses.**

Procedures: The Procedures and Surgeries Documentation form is found on page three of the Follow-up questionnaire.

"Check here if you have had No Medical Procedures or Surgeries in the last 5 years": If this box is checked on the questionnaire, and there are no procedures and surgeries reported on the rest of the form, **[Click]** on the check box to enter a check into the Illnesses and Procedures screen. **Proceed to the [Medications and Supplements] File Tab.**

> **If procedures and/or surgeries are reported:** The form entry is identical to that of the Illness Documentation form entry of the Initial Questionnaire. **Please refer to Section 7, Illnesses+, for a complete description of entering procedures and/or surgeries.**

Note: If a surgery is listed, a corresponding illness should either exist already in the illness table, or be added along with the surgery report. For instance, if a cataract surgery is reported, an illness record of "Cataracts " should be added to the illness table if one is not yet in place. **Enter all Surgeries and/or Procedures reported.**

The Illnesses and Procedures section is now complete. **[Click] on the Medications and Supplements file tab.**

Medications and Supplements: The Prescription Medications Documentation form is found on the bottom of the third page of the Follow-up questionnaire. The form entry is identical to that of the Medication Documentation form entry of the Initial Questionnaire. **Please refer to Section 8, Medications+, for a complete description of entering prescription medications.**

Supplements: The Supplements form (vitamin or mineral supplements, herbal remedies or non-prescription drugs) is found on the fourth and last page of the questionnaire. The form entry is identical to that of the Medication Documentation form entry of the Initial Questionnaire. **Please refer to Section 8, Medications+, for a complete description of entering prescription medications.**

Note: After entering any new Illness, Procedure or Medication, check the Patient Doctor file and verify that the doctor/clinic entered with the new record exists in the Patient Doctor File.

> **Access Patient file: [Click]** on the **Patient** window behind the Follow up Questionnaire window to access the participant's file.
> **[Click]** on the **[Doctors]** file tab.
> Locate the Doctor/Clinic in the Patient's Doctor file.

If the Doctor/Clinic is not in the Patient's Doctor file, please refer to Section 9 in the Initial Questionnaire Entry Protocol for a complete description of entering the Doctor/Clinic into the Patient Doctor file.

If any answer is blank, unclear or incorrect call the participant as soon as possible to complete the questionnaire.

The Follow-Up Questionnaire is now complete.

Close the Follow-up form Window: [Click] on the **[X]** in the upper right hand corner of the form.
Close the Patient File: [Click] the **[X]** in the top right hand corner of the Patient File window. Use the horizontal scroll bar at the bottom of the screen to access the **[X].**

A SElectWarning may pop up, stating that **frm.Patient** has been updated and should changes be saved. Choose **[YES].** (This means ECW is working!!!)

To Continue Working in Select: Choose **[Edit Patient]** from the SElectPatient Menu to continue entering data on other patients.

To Close Select: [Click] the **[X]** in the top right hand corner of the window.

P:\SeLECT study\Protocols\forms entry\Follow-up_Quest_Entry.doc

Urology Questionnaire:

The Urology questionnaire entry screen is broken up into four sections, which correspond to the numbers on the questionnaire form. The easiest method of entering this page is to use the **[Tab]** button to move from field to field, rather than pointing and clicking with the mouse. The screen will default on the last urology form entered. **[Click]** on the Full Screen button of the SELECT screen, or manually expand the window to access the record scroll bar of the Urology screen.

Verify the Distribution Number: Located on the right at the top of both the entry screen and the form to be entered. The Distribution Number is assigned to each form by the study nurse and is logged into the patient's file before it is mailed to the study patient. It is linked to all information entered from a given form into the patient's data file and will be used as the source of the information.

Verify the Patient's Name
Verify the Patient ID: Located in the top left-hand corner of the Urology entry screen, and under the questionnaire date of the Urology form. **This field is not entered by the user.** It is a unique, sequential number assigned to the patient by the computer. It represents the order in which the patient was randomized into the study. After a patient is randomized and entered into the Patient's table, the program then arranges the table in alphabetical order to facilitate data entry.

Verify the Urology Questionnaire Record Number: The user should always verify that he/she is at the end of the file before entering any additional records. The end of the file can be ascertained by checking the status on the **record scroll bar**, located in the bottom of the screen. Make sure that the record scroll bar is at the end of the file. If not, **[Click]** the **[▸*]** button on the right side of the bar to create a new record.

> **Quest Date:** This is the date of the form, located in the top right hand corner of the questionnaire. Enter all dates numerically as MMDDYY, the program will automatically add date slashes and correct for Y2K.
> **Doctor:** Use the pull down menu to find the physician associated with the event, or type in his/her name. Highlight the physician's name and press **[Enter].**
> **If the patient only lists a hospital or clinic and no doctor:**
>
> > **Enter:** the **Department of Medical Records** option, from the **Doctors** pull down menu.
> > **Attach**: the appropriate Clinic or Hospital from the **Clinics** pull down menu. (This circuitous method is in response to inefficient programming.)

Note: This method should also be used if the medical records for the event will be obtained from the hospital and not the physician, or if the patient sees several doctors at the same facility.

In the event that <u>both</u> the Physician and Clinic are not located in the Doctors or Clinic Tables, please see Appendix [XX] Adding Doctors/Clinics.

Section A, questions 1-8.

1) **Appetite:** type in the number corresponding to one of these four responses:

   1-Good
   2- Fair
   3 -Poor
   9 -Missing

The program will choose the correct response from the pull down menus and the full answer will appear in the field without any additional typing. The user also has the option of choosing the correct response from the pull down menu, or manually typing in the answer.

2) **Current Weight:** enter in pounds
3) **Weight change:** Enter one of following four responses:

   1-Weight Loss
   2-Weight Gain
   3 -No Change
   9 -Missing

   Pounds change: Any weight gain or loss entered in pounds

4) **Wants to lose weight:** [YES/NO].

Note: The easiest method of entering the **[YES/NO]** information queries is to type one of these three responses:

   1-Yes
   0 -No
   9 -Missing

5) **Experience any:** If any of these four items are checked on the questionnaire, **[Click]** on the corresponding check boxes on the entry screen to enter a response.

-Nausea
-Vomiting
-Fever
-Chills

Do not check any boxes if [No Symptoms] is checked.

6) **New aches or pains:** [YES/NO].
7) **Numbness**: [YES/NO].
Numbness Location: use this text box to describe the reported area of numbness

Section A is now complete. Please [Click] on the Section B file tab.

Section B, questions 8-14

8) **Urinating at night:** Enter one of the following responses:

0- None
1- 1 time
2- 2 times
3- 3 times
4- 4 times
5- 5 times
6- 6 or more times
9- Missing

9) **Not emptying bladder:** enter one of the following responses:

1- Not at all
2- Less than 1 in 5
3- Less than half
4- About half the time
5- More than half
6- Almost always

Note: Questions 10-14 have the same responses to the questions as Question 9. Use the same **[1-6]** responses to enter the information from the questionnaire.

10) **Frequent urinating:** [1-6]
11) **Stopped and Started:** [1-6]
12) **Urgent need:** [1-6]
13) **Weak Stream:** [1-6]
14) **Push or strain:** [1-6]

Section B is now complete. Please [Click] on the Section C File Tab.

Section C, questions 15-23.

15) **Weakness in Arms:** [YES/NO]
16) **Weakness in Legs:** [YES/NO]
17) **Blood in Urine:** There are no numeric entries associated with the correct response as in previous questions. The user must use the pull down menu and choose one of the following responses, which correspond to the check box answers on the questionnaire form:

-Initially
-Finishing
-Total
-Clots
-None
-Missing

18) **Stream Rating:** Choose one of the following responses:

1- good
2- fair
3- weak
4- steady
5- intermittent
6- double
7- missing

19) **Stress incontinence:** [YES/NO] If answer is **[NO]**, proceed to question 21
20) **Incontinence rating:** choose one of the following responses **ONLY** if question 19 was answered **[YES]**:

-stable
-improved
-worse
-missing

Number of pads: enter number in text box **ONLY** if question 19 was answered **[YES].**

21) Had sex lately: [YES/NO]
22) Treated for Infection: [YES/NO]
23) Used catheter lately: [YES/NO]

Section C is now complete. Please [Click] on the Section D File Tab.

Section D, questions 24-27.

24) Last appointment: Enter MM/DD/YY, program will correct for Y2K.
25) Next appointment: Enter same as question 24
–OR-
[Click] on the check box for **No appointment scheduled.**

26) Date of last biopsy: a text field, enter date as MM/DD/YY.
27) Date of last exam: same as question 26.
28) Comments: If applicable, type in exactly as written on questionnaire.

If Illnesses, Procedures, Medications and/or Supplements are reported:

[Click] on the Patient Window behind the Urology Questionnaire to access the **[Illness]** and/or **[Medications]** file tabs.

[Click] on the appropriate file tab (Illness or Medications)
Verify the Record Number: The program will automatically update the number of records in these files and will create an empty record at the end of the file for future entry. **However, the user should always verify that he/she is at the end of the file before entering any additional records**. The empty record at the end of each file is proceeded by the symbol **[*]**. The end of the file can also be ascertained by checking the status on the **record scroll bar**, located in the bottom left-hand corner of the screen. Make sure that the record scroll bar is at the end of the file. If not, **[Click]** the **[▸*]** button on the right side of the bar to create a new record.

Add the Distribution Number from the Urology questionnaire: The report must be attached to a source for future documentation. Use the pull down menu in the **Dist** column of the empty record to access a list of the distribution numbers assigned to the patient. Highlight the appropriate distribution number and press **[Enter].** Continue entering the record.

Please refer to Sections 7 and 8 in the Initial Questionnaire Entry Protocol for a complete description of entering Illnesses, Procedures and Surgeries, Medications and Supplements.

Note: After entering any new Illness, Procedure or Medication , check the Patient Doctor file and verify that the doctor/clinic entered with the new record exists in the Patient Doctor File.

[Click] on the Doctors file tab.
Locate the Doctor/Clinic in the Patient's Doctor file.

If the Doctor/Clinic is not in the Patient's Doctor file, please refer to Section 9 in the Initial Questionnaire Entry Protocol for a complete description of entering the Doctor/Clinic into the Patient Doctor file.

The Urology Questionnaire is now complete.

Close the Urology form Window: [Click] on the **[X]** in the upper right hand corner of the form.
Close the Patient File: [Click] the **[X]** in the top right hand corner of the Patient File window. Use the horizontal scroll bar at the bottom of the screen to access the **[X].**

A Select Warning may pop up, stating that **frm.Patient** has been updated and should changes be saved. Choose **[YES].** (This means ECW is working!!!)

To Continue Working in Select: Choose **[Edit Patient]** from the SELECT Patient Menu to continue entering data on other patients.

To Close Select: [Click] the **[X]** in the top right hand corner of the window.

APPENDIX [XX]
ADDING/EDITING DOCTORS FOR SELECT

All physicians, hospitals and clinics must be added to the Doctor's table before they can be attached to any patient illnesses and/or medications, and also before they can be attached to the Patient Doctor Table. Physicians and clinics can be added to the Doctor's table through the **Patient File**, under any of the following file tabs: **[Doctors]**, **[Illnesses]**, **[Medications]**, or **[Questionnaires]**. Doctors are added within the three Questionnaire entry programs under the following three file tabs: **[Illnesses and Procedures]**, **[Medications and Supplements]**, or **[Doctors].**

All modifications to existing doctor records must also be done by accessing the **Doctor** table through any of the previously mentioned Patient file tabs. **Note:** The Doctor table can be accessed and modified independent of the patient through any of the previously listed file tabs. This means that a user could add/edit the Doctor's table, while in a specific Patient file, without attaching the doctor record to the patient.

Open Select Either by clicking on the **Select icon** or by going to **M:\Select\SSentry.mdb** and opening the program. Microsoft Access must be installed on the user's computer to be able to access these programs.

Highlight the name of the desired patient. This activates the **[Edit Patient]** button, which allows browsing and editing of all patient files and allows additions and changes to the Doctor table. **[Click] the [Edit Patient] button**. It is now possible to add/edit the Doctor table.

Adding Physicians:

Click on one of the following file tabs: [Doctors], [Illnesses], [Medications], or [Questionnaires]

Note: The Add Doctor entry program is identical throughout all of these file tabs. However, a user must choose the [Questionnaire] file tab if he/she is:

Entering a Questionnaire

Adding a doctor record that was originally reported on a questionnaire. This preserves the source of the original information.

Locate the [Doctors] button: Found near the bottom of the screen. **Click on the [Doctors] button.**

Search: Enter the name of the physician, or use the pull down menu to ascertain that the physician (hospital, clinic) is not already in the Doctors table. **Avoid Duplications!**

Find the physician's complete address: Use the following resources to complete every field in the Doctor's table:

Resources for finding Physicians:

Information from the Patient's questionnaire forms.
The Yellow Pages: if convenient
Directory Assistance:
Internet Yellow Pages: These are very handy, as they list the full address of the physician and also often list the doctor's specialty and fax number. A good Web page is **GTE Superpages©- Internet Services** at http://yp.gte.net/
AMA Licensing Boards: These lists can be found through Directory Assistance or the Internet. They list the physician's specialty, address and the status of their license. Also, some states publish these lists in books, which can be ordered from the state's licensing board. However, the books can be hard to obtain and are only updated once a year.
Calls to the Physician's office:
Calls to the Patient:

Verify the record number: The end of the file can be ascertained by checking the status on the record scroll bar, located in the bottom of the screen. Make sure that the record scroll bar is at the end of the file. If not, Click the [▸*] button on the right side of the bar to create a new record.

Physician Record Entry:

Dr ID: This field is not entered by the user. It is a unique, sequential number assigned to the record by the computer. It represents the order in which the record was entered into the table. After a record is entered into the Doctor's table, the program arranges the table in alphabetical order to facilitate data entry.
Last Name:
First Name:
Middle Name:
Address: Use this field if the physician practices under a physician's group or under a business name.
Address: Use this field for the street address of the Physician.
City:
Zip Code: five-digit numeric field
State: Enter the two-digit state abbreviation or use the pull down menu to choose the correct state.
Phone Number: Enter the area code and seven-digit number, without parentheses or dashes. The program adds these.

Note: The preceding eight fields (nine if the physician's address includes a business name) must be completed for the physician record to be considered valid.

Fax Number: Enter the area code and seven-digit number, without parentheses or dashes. The program adds these.
Specialty: Choose from the pull down menu. If the physician's specialty is not known, choose **99-Not Specified.**
Clinic: A physician can be attached to a clinic or hospital. This is useful if the doctor either sees the study patient in a clinic or hospital or works in such a facility. It is more efficient to request patient medical records from the clinic or hospital, rather than the physician. Therefore, the Clinics/Hospital table is separate from the Doctor's table.

To Attach a Clinic or Hospital to a Physician:
[Click] on the [Clinics] button
Locate the Clinic or Hospital from the table and press [Enter]

Note: If the desired Clinic or Hospital is not located in the Clinics/Hospitals table, the user must first add the facility to the table before he/she can attach it to any physicians from the Doctors table. **Please see the Adding Clinics/Hospitals Entry below for a detailed description of entering clinics and hospitals into the Clinics/Hospitals table.**

Not Active: [Click] on this Check box if the physician has retired or has moved from the area and no longer sees study patients.

The new physician record is now complete. The record will be entered upon exiting the Doctors table.

Close the Doctor's table: [Click] the **[X]** in the top right hand corner of the window.

Adding Hospitals and Clinics:

[Click] on one of the following file tabs: [Doctors], [Illnesses], [Medications], or [Questionnaires].

Locate the [Clinics] button: Found near the bottom of the screen. **Click on the [Clinics] button.**

Search: Enter the name of the facility, or use the pull down menu to ascertain that the hospital or clinic is not already in the Clinics/Hospitals table. Avoid Duplications!

Find the facility's complete address: Complete every field in the Clinics/Hospitals table. Please refer to **Adding Physicians-Resources for finding physicians** for additional information.

Verify the record number: The end of the file can be ascertained by checking the status on the record scroll bar, located in the bottom of the screen. Make sure that the record scroll bar is at the end of the file. If not, Click the **[▸*]** button on the right side of the bar to create a new record.

Clinic/Hospital Record Entry:

Clinic ID: This field is not entered by the user. It is a unique, sequential number assigned to the record by the computer. It represents the order in which the record was entered into the table. After a record is entered into the Clinic/Hospitals table, the program arranges the table in alphabetical order to facilitate data entry.
Clinic Name:
Clinic Contact: Our Clinic Coordinator if the facility is one of our participating clinics. Otherwise, any staff member that may facilitate the collection of patient medical records.
Phone Number: See below.
Fax Number: Enter the area code and seven-digit number, without parentheses or dashes. The program adds these.
Street: Use this field for any department or business names associated with the facility
Street: Use this field for the street address of the facility.
City:
Zip Code: five-digit numeric field
State: Enter the two-digit state abbreviation or use the pull down menu to choose the correct state.

The new clinic/hospital record is now complete. The record will be entered upon exiting the Clinics/Hospitals table.

Close the Clinics/Hospitals table: [Click] the **[X]** in the top right hand corner of the window.

Editing Physician records:

[Click] on one of the following: [Doctors], [Illnesses], [Medications], or [Questionnaires]
Locate the [Doctors] button: Found near the bottom of the screen. **Click on the [Doctors] button.**

Search: Enter the name of the physician, or use the pull down menu.
Verify that the physician is correct: The user will be overwriting data in the database. Avoid mistakes and incorrect information!

Editing: Tab through the fields, modifying if necessary.

Close the Doctor's table: [Click] the **[X]** in the top right hand corner of the window.

Editing Hospitals and Clinics:

[Click] on one of the following: [Doctors], [Illnesses], [Medications], or [Questionnaires]
Locate the [Clinics] button: Found near the bottom of the screen. **[Click] on the [Clinics] button.**

Search: Enter the name of the facility, or use the pull down menu.
Verify that the clinic/hospital is correct: The user will be overwriting data in the database. Avoid mistakes and incorrect information!

Editing: Tab through the fields, modifying if necessary.

Close the Clinics/Hospitals table: [Click] the **[X]** in the top right hand corner of the window.

To Exit:

Close the Questionnaire: In the questionnaire, [Click] the **[X]** in the top right hand corner of the window.

Close the Patient File: [Click] the **[X]** in the top right hand corner of the Patient File window. Use the horizontal scroll bar at the bottom of the screen to access the **[X].**

A SELECTWarning may pop up, stating that **frm.Patient** has been updated and should changes be saved. Choose **[YES].** (This means ECW is working!!!)

To Continue Working in SELECT: Choose **[Edit Patient]** from the SElectPatient Menu to continue entering data on other patients.

To Close SELECT: [Click] the **[X]** in the top right hand corner of the window

Protocol for Entering SmithKline Beecham Lab Results

Values within Normal Range

1. Open **SELECT** Program
2. Select patient
3. Select "Blood" tab
4. Select corresponding lab number
5. Select SMAC-18
6. Enter values
7. Select CBC (when applies)
8. Enter values

Values Not within Normal Range

1. **Immediately photocopy lab results and fax to participant's Dr.**
2. **If prompted that values are 1.5X normal range notify Nurse on duty**
3. Open **SELECT** Program
4. Select patient
5. Select "Blood" tab
6. Select corresponding lab number
7. Select SMAC-18
8. Enter values
9. Select CBC (when applies)
10. Enter values

SELECT BLOOD KIT TYPES

Type	Type of Vacutainer	Qty.	Type of Sample
K1	Sodium Heparin	1	Selenium
	SST(9.5ml)	2	Total PSA
			CMP
			Chrom-A
			Lycopene
			Vit.E
K2	Sodium Heparin	1	Selenium
	SST(9.5ml)	1	Total PSA
			Chrom-A
K3	Sodium Heparin	1	Selenium
	SST(6 ml)	2	Total PSA
			CMP
			Chrom-A

P:\SeLECT Study\laboratoy\Blood Kits\Select BLOOD KIT TYPES.doc

SELECT BLOOD KIT SCHEDULE

Visit Number	Kit Type	Checklist
1	1	
2	2	
3	3	
4	2	
5	3	
6	2	

P:\SElect Study\Protocols\Laboratory and BKs\Select BLOOD KIT SCHEDULE.doc

PROTOCOL FOR ASSEMBLING BLOOD KITS (Kit 1)

1. Blood Kit Materials
   - 1, zip-lock baggie
   - 1, **8ml**. Blue top sodium heparin vacutainer tube
   - 2, **9.5ml** Tiger top SST vacutainer
   - 8, aliquot tubes
   - 1, specimen transfer pipet
   - absorbent paper
   - sample number labels

2. Labeling Vacutainers

   - affix all labels length-wise down the vacutainer.
   - affix the label marked as **Se Vac** onto the blue top Sodium Heparin tube.
   - affix the label marked as **PSA Vac** onto the 9.5ml tiger top SST tube.
   - affix the label marked as **Lyco/vE Vac** onto the same 9.5ml tiger top SST tube.
   - affix the label marked as **Chrom Vac** onto the other 9.5ml tiger top SST tube.
   - affix the label marked as **CMP Vac** onto this same 9.5ml tiger top SST tube.
   - place a piece of tape over the entire label, overlapping about 0.5 cm on each end.
   - using a water-proof lab marker, write the patient's treatment number in the space provided

3. Labeling Aliquots

   - affix the labels marked as **Se 1** and **Se 2** onto two clear aliquot tubes (make sure the aliquots don't have white marking on the outside, or residual liquid on the inside, these are for Vit. E analysis)
   - affix the label marked as **PSA** onto the purple top aliquot
   - affix the labels marked as **Chrom-A** onto two clear aliquots
   - affix the label marked as **Vit.E** onto an aliquot which has white markings on the outside
   - affix the label marked as **Lycopene** onto a clear aliquot
   - affix the label marked as **CMP** onto a clear aliquot
   - place a piece of tape around the affixed label, again overlap by about 0.5cm on each end
   - using a water-proof lab marker, write the patient's treatment number in the space provided

4. Labeling the Baggie
   - affix the label marked as Sample Bag onto the lower left of the baggie
   - write the Kit type number in the space provided

5. Packaging Materials
    - styrofoam box
    - cardboard box
    - foam packing
    - refrigerant pack
    - **Fed-Ex USA Airbill** (making sure that under ***section 4a***: FedEx Priority Overnight is marked, and under ***section 5***: Other Pkg. Is marked)
        - This form should already be prepared with our address filled in under ***To***, along with our account number.
    - Blue **Procedure for Drawing, Processing, and Mailing Plasma and Blood Specimens** form
    - Yellow **Laboratory Form**
    - Plastic **Diagnostic Specimen Envelope**
    - Cover letter

6. Tracking Blood Kit
    - on blood kit tracking form write **patient's name, where the kit was sent, treatment number, lab number** (located on the labels), **date package was sent**, and **Fed-Ex tracking number** (located at the top of the **Fed-Ex Airbill)**

7. Assembling the Blood Kit for shipment
    - assemble cardboard box leaving the top open
    - place all the vacutainers, aliquots, transfer pipet in the labeled baggie with a piece of 2-ply absorbent paper
        - the absorbent paper is 6-ply and can be separated into three 2-ply pieces
    - place the full baggie into the styrofoam box along side the coolant pack, place the lid on the box
    - place the styrofoam box inside the cardboard box
    - fold the **Diagnostic Specimen Envelope** in half 3 times and slide down the width of the cardboard box..
    - fold the yellow **Laboratory Form**, the blue **Procedure for Drawing, Processing, and Mailing Plasma and Blood Specimens** and the cover letter in half and place behind the styrofoam box
    - fold the **Fed-Ex USA Airbill** and place behind the styrofoam box as well.
    - Fold down the lid of the cardboard box and place two pieces of packing tape over each end of the box.
    - Affix the pre-printed participant label on the front of the box
    - Place the box near the out-going mail basket

8. Special Shipping
    - if blood kit needs to be shipped overnight, call Federal Express (1-800-463-3339) and arrange for a pick-up

PROTOCOL FOR ASSEMBLING BLOOD KITS (Kit 2)

1. Blood Kit Materials
   - 1, zip-lock baggie
   - 1, **8ml**. Blue top sodium heparin vacutainer tube
   - 1, **9.5ml** Tiger top SST vacutainer
   - 5, aliquot tubes
   - 1, specimen transfer pipet
   - absorbent paper
   - sample number labels

2. Labeling Vacutainers

   - affix all labels length-wise down the vacutainer.
   - affix the label marked as **Se Vac** onto the blue top Sodium Heparin tube.
   - affix the label marked as **PSA Vac** onto the 9.5ml tiger top SST tube.
   - affix the label marked as **Chrom Vac** onto the same 9.5ml tiger top SST tube.
   - place a piece of tape over the entire label, overlapping about 0.5 cm on each end.
   - using a water-proof lab marker, write the patient's treatment number in the space provided

3. Labeling Aliquots

   - affix the labels marked as **Se 1** and **Se 2** onto two clear aliquot tubes (make sure the aliquots don't have white marking on the outside, or residual liquid on the inside, these are for Vit. E analysis)
   - affix the label marked as **PSA** onto the purple top aliquot
   - affix the labels marked as **Chrom-A** onto two clear aliquots
   - place a piece of tape around the affixed label, again overlap by about 0.5cm on each end
   - using a water-proof lab marker, write the patient's treatment number in the space provided

4. Labeling the Baggie
   - affix the label marked as Sample Bag onto the lower left of the baggie
   - write the Kit type number in the space provided

5. Packaging Materials
   - styrofoam box
   - cardboard box
   - foam packing
   - refrigerant pack
   - **Fed-Ex USA Airbill** (making sure that under ***section 4a***: FedEx Priority Overnight is marked, and under ***section 5***: Other Pkg. Is marked)
     - This form should already be prepared with our address filled in under ***To***, along with our account number.
   - Blue **Procedure for Drawing, Processing, and Mailing Plasma and Blood Specimens** form
   - Yellow **Laboratory Form**
   - Plastic **Diagnostic Specimen Envelope**
   - Cover letter

6. Tracking Blood Kit
   - on blood kit tracking form write **patient's name, where the kit was sent, treatment number, lab number** (located on the labels), **date package was sent**, and **Fed-Ex tracking number** (located at the top of the **Fed-Ex Airbill**)

7. Assembling the Blood Kit for shipment
   - assemble cardboard box leaving the top open
   - place all the vacutainers, aliquots, transfer pipet in the labeled baggie with a piece of 2-ply absorbent paper
     - the absorbent paper is 6-ply and can be separated into three 2-ply pieces
   - place the full baggie into the styrofoam box along side the coolant pack, place the lid on the box
   - place the styrofoam box inside the cardboard box
   - fold the **Diagnostic Specimen Envelope** in half 3 times and slide down the width of the cardboard box..
   - fold the yellow **Laboratory Form**, the blue **Procedure for Drawing, Processing, and Mailing Plasma and Blood Specimens** and the cover letter in half and place behind the styrofoam box
   - fold the **Fed-Ex USA Airbill** and place behind the styrofoam box as well.
   - Fold down the lid of the cardboard box and place two pieces of packing tape over each end of the box.
   - Affix the pre-printed participant label on the front of the box
   - Place the box near the out-going mail basket

8. Special Shipping
   - if blood kit needs to be shipped overnight, call Federal Express (1-800-463-3339) and arrange for a pick-up

PROTOCOL FOR ASSEMBLING BLOOD KITS (Kit 3)

1. Blood Kit Materials
   - 1, zip-lock baggie
   - 1, **8ml** Blue top sodium heparin vacutainer tube
   - 2, **6ml** Tiger top SST vacutainer
   - 6, aliquot tubes
   - 1, specimen transfer pipet
   - absorbent paper
   - sample number labels

2. Labeling Vacutainers

   - affix all labels length-wise down the vacutainer.
   - affix the label marked as **Se Vac** onto the blue top Sodium Heparin tube.
   - affix the label marked as **PSA Vac** onto a 6ml tiger top SST tube.
   - affix the label marked as **CMP Vac** onto the same 6ml tiger top SST tube.
   - affix the label marked as **Chrom Vac** onto the other 6ml tiger top SST tube.
   - place a piece of tape over the entire label, overlapping about 0.5 cm on each end.
   - using a water-proof lab marker, write the patient's treatment number in the space provided

3. Labeling Aliquots

   - affix the labels marked as **Se 1** and **Se 2** onto two clear aliquot tubes (make sure the aliquots don't have white marking on the outside, or residual liquid on the inside, these are for Vit. E analysis)
   - affix the label marked as **PSA** onto the purple top aliquot
   - affix the label marked as **CMP** onto a clear aliquot tube
   - affix the labels marked as **Chrom-A** onto two clear aliquots
   - place a piece of tape around the affixed label, again overlap by about 0.5cm on each end
   - using a water-proof lab marker, write the patient's treatment number in the space provided

4. Labeling the Baggie
   - affix the label marked as Sample Bag onto the lower left of the baggie
   - write the Kit type number in the space provided

SELECT Off-Site Blood Draw Protocol (Visit #1)

BLOOD DRAW (please draw in the following order)

1. Fill navy blue top (8ml) Sodium Heparin vacutainer labeled as **Se.**
2. Fill tiger top (9.5ml) SST vacutainer labeled as **PSA** and **Chrom-A.**
3. Fill tiger top (9.5ml) SST vacutainer labeled as **Lyco/Vit. E and CMP.**

BLOOD PROCESSING

*** FOR OPTIMAL RESULTS, IT IS SUGGESTED THAT THE SST VACUTAINERS SIT FOR 20MIN WITH PATIENT'S WHOLE BLOOD BEFORE THEY ARE SPUN DOWN. IN ADDITION, PLEASE INVERT THE BLUE TOP SODIUM HEPARIN VACUTAINER 8-10 TIMES AFTER THEY ARE FILLED WITH WHOLE BLOOD. ***

1. Spin down tiger top SST vacutainer labeled as **PSA** and **Lyco/vE Vac.**
2. Spin down tiger top SST vacutainer labeled as **Chrom and CMP Vac.**
3. Using a transfer pipet, transfer serum from SST vacutainer labeled **PSA** and **Lyco/vE** into the purple top aliquot tube labeled as **PSA,** the white striped aliquot tube labeled **Lycopene** and the clear aliquot tube labeled as **Vit. E.**
4. Using a transfer pipet, transfer serum for SST vacutainer labeled **Chrom** and **CMP** into the aliquot tubes labeled as **CMP** and **Chrom-A.**

END RESULTS FOR MAILING

1. 1 navy blue top Sodium Heparin vacutainer labeled as **Se** with approximately 8ml of whole blood.
2. 1 purple top aliquot tube labeled as **PSA** with 1ml of serum.
3. 2 aliquot tubes labeled as **Chrom-A** with 1ml of serum in each.
4. 1 aliquot tube labeled as **Lyco.** with 1ml of serum.
5. 1 white striped aliquot tube labeled as **Vit. E** with 1ml of serum.
6. 1 aliquot tube labeled as **CMP** with 1ml of serum.

We realize that variability in patient blood draw volume will occur. Please draw blood in the specified order. Thank you.

P:\SeLECT Study\laboratoy\OffSite Blood Draw\Select_Blood Draw Protocol #1.doc

SELECT Off-Site Blood Draw Protocol (Visit #2)

BLOOD DRAW (please draw in the following order)

1. Fill navy blue top (8ml) Sodium Heparin vacutainer labeled as **Se.**
2. Fill tiger top (9.5ml) SST vacutainer labeled as **PSA** and **Chrom-A.**

BLOOD PROCESSING

*** FOR OPTIMAL RESULTS, IT IS SUGGESTED THAT THE SST VACUTAINERS SIT FOR 20MIN WITH PATIENT'S WHOLE BLOOD BEFORE THEY ARE SPUN DOWN. IN ADDITION, PLEASE INVERT THE BLUE TOP SODIUM HEPARIN VACUTAINERS 8-10 TIMES AFTER THEY ARE FILLED WITH WHOLE BLOOD. ***

1. Spin down tiger top SST vacutainer labeled **PSA** and **Chrom-A.**
2. Using a transfer pipet, transfer serum from the SST vacutainer labeled **PSA** and **Chrom-A** into the purple top aliquot tube labeled as **PSA,** and into two clear aliquot tubes labeled as **Chrom-A.**

END RESULTS FOR MAILING

1. 1 navy blue top Sodium Heparin vacutainer labeled as **Se** with approximately 8ml of whole blood.
2. 1 purple top aliquot tube labeled as **PSA** with 1ml of serum in each.
3. 2 aliquot tubes labeled as **Chrom-A** with 1ml of serum in each.

We realize that variability in patient blood draw volume will occur. Please draw blood in the specified order. Thank you.

P:\SeLECT Study\laboratoy\OffSite Blood Draw\Select_Blood Draw Protocol #2.doc

SELECT Off-Site Blood Draw Protocol (Visit #3)

BLOOD DRAW (please draw in the following order)

1. Fill navy blue top (8ml) Sodium Heparin vacutainer labeled as **Se**.
2. Fill tiger top (6ml) SST vacutainer labeled as **PSA**, and **CMP.**
3. Fill tiger top (6ml) SST vacutainer labeled as **Chrom-A**.

BLOOD PROCESSING

*** FOR OPTIMAL RESULTS, IT IS SUGGESTED THAT THE SST VACUTAINERS SIT FOR 20MIN WITH PATIENT'S WHOLE BLOOD BEFORE THEY ARE SPUN DOWN. IN ADDITION, PLEASE INVERT THE BLUE TOP SODIUM HEPARIN VACUTAINERS 8-10 TIMES AFTER THEY ARE FILLED WITH WHOLE BLOOD. ****

1. Spin down tiger top SST vacutainer labeled **PSA** and **CMP**.
2. Spin down tiger top SST vacutainer labeled as **Chrom-A**.
3. Using transfer pipet, transfer serum from SST vacutainer into the purple top aliquot tubes labeled as **PSA** and into the clear aliquot tube labeled as **CMP**.
4. Using transfer pipet, transfer serum from SST vacutainer into two aliquout tubes labeled as **Chrom-A**.

END RESULTS FOR MAILING

1. 1 navy blue top Sodium Heparin vacutainer labeled as **Se** with approximately 8ml of whole blood.
2. 1 purple top aliquot tub labeled as **PSA** with 1ml of serum.
3. 1 aliquot tube labeled as **CMP** with 1ml of serum.
4. 2 aliquot tubes labeled as **Chrom-A** with 1ml of serum in each.

We realize that variability in patient blood draw volume will occur. Please draw blood in the specified order. Thank you.

P:\SeLECT Study\laboratoy\OffSite Blood Draw\Select_Blood Draw Protocol #3.doc

SELECT Off-Site Blood Draw Protocol (Visit #4)

BLOOD DRAW (please draw in the following order)

1. Fill navy blue top (8ml) Sodium Heparin vacutainer labeled as **Se.**
2. Fill tiger top (9.5ml) SST vacutainer labeled as **PSA** and **Chrom-A.**

BLOOD PROCESSING

*** FOR OPTIMAL RESULTS, IT IS SUGGESTED THAT THE SST VACUTAINERS SIT FOR 20MIN WITH PATIENT'S WHOLE BLOOD BEFORE THEY ARE SPUN DOWN. IN ADDITION, PLEASE INVERT THE BLUE TOP SODIUM HEPARIN VACUTAINERS 8-10 TIMES AFTER THEY ARE FILLED WITH WHOLE BLOOD. ***

1. Spin down tiger top SST vacutainer labeled **PSA** and **Chrom-A.**
2. Using a transfer pipet, transfer serum from the SST vacutainer labeled **PSA** and **Chrom-A** into the purple top aliquot tube labeled as **PSA,** and into two clear aliquot tubes labeled as **Chrom-A.**

END RESULTS FOR MAILING

1. 1 navy blue top Sodium Heparin vacutainer labeled as **Se** with approximately 8ml of whole blood.
2. 1 purple top aliquot tube labeled as **PSA** with 1ml of serum in each.
3. 2 aliquot tubes labeled as **Chrom-A** with 1ml of serum in each.

We realize that variability in patient blood draw volume will occur. Please draw blood in the specified order. Thank you.

P:\SeLECT Study\laboratoy\OffSite Blood Draw\Select_Blood Draw Protocol #2.doc

SELECT Off-Site Blood Draw Protocol (Visit #5)

BLOOD DRAW (please draw in the following order)

1. Fill navy blue top (8ml) Sodium Heparin vacutainer labeled as **Se**.
2. Fill tiger top (6ml) SST vacutainer labeled as **PSA**, and **CMP.**
3. Fill tiger top (6ml) SST vacutainer labeled as **Chrom-A**.

BLOOD PROCESSING

*** FOR OPTIMAL RESULTS, IT IS SUGGESTED THAT THE SST VACUTAINERS SIT FOR 20MIN WITH PATIENT'S WHOLE BLOOD BEFORE THEY ARE SPUN DOWN. IN ADDITION, PLEASE INVERT THE BLUE TOP SODIUM HEPARIN VACUTAINERS 8-10 TIMES AFTER THEY ARE FILLED WITH WHOLE BLOOD. ***

1. Spin down tiger top SST vacutainer labeled **PSA** and **CMP**.
2. Spin down tiger top SST vacutainer labeled as **Chrom-A**.
3. Using transfer pipet, transfer serum from SST vacutainer into the purple top aliquot tubes labeled as **PSA** and into the clear aliquot tube labeled as **CMP**.
4. Using transfer pipet, transfer serum from SST vacutainer into two aliquout tubes labeled as **Chrom-A**.

END RESULTS FOR MAILING

1. 1 navy blue top Sodium Heparin vacutainer labeled as **Se** with approximately 8ml of whole blood.
2. 1 purple top aliquot tub labeled as **PSA** with 1ml of serum.
3. 1 aliquot tube labeled as **CMP** with 1ml of serum,in each.
4. 2 aliquot tubes labeled as **Chrom-A** with 1ml of serum in each.

We realize that variability in patient blood draw volume will occur. Please draw blood in the specified order. Thank you.

SELECT Off-Site Blood Draw Protocol (Visit #6)

BLOOD DRAW (please draw in the following order)

1. Fill navy blue top (8ml) Sodium Heparin vacutainer labeled as **Se.**
2. Fill tiger top (9.5ml) SST vacutainer labeled as **PSA** and **Chrom-A.**

BLOOD PROCESSING

*** FOR OPTIMAL RESULTS, IT IS SUGGESTED THAT THE SST VACUTAINERS SIT FOR 20MIN WITH PATIENT'S WHOLE BLOOD BEFORE THEY ARE SPUN DOWN. IN ADDITION, PLEASE INVERT THE BLUE TOP SODIUM HEPARIN VACUTAINERS 8-10 TIMES AFTER THEY ARE FILLED WITH WHOLE BLOOD. ***

1. Spin down tiger top SST vacutainer labeled **PSA** and **Chrom-A.**
2. Using a transfer pipet, transfer serum from the SST vacutainer labeled **PSA** and **Chrom-A** into the purple top aliquot tube labeled as **PSA,** and into two clear aliquot tubes labeled as **Chrom-A.**

END RESULTS FOR MAILING

1. 1 navy blue top Sodium Heparin vacutainer labeled as **Se** with approximately 8ml of whole blood.
2. 1 purple top aliquot tube labeled as **PSA** with 1ml of serum in each.
3. 2 aliquot tubes labeled as **Chrom-A** with 1ml of serum in each.

We realize that variability in patient blood draw volume will occur. Please draw blood in the specified order. Thank you.

P:\SeLECT Study\laboratoy\OffSite Blood Draw\Select_Blood Draw Protocol #2.doc

SELECT Off-Site Blood Draw Protocol (Visit A.E.)

BLOOD DRAW (please draw in the following order)

1. Fill navy blue top (8ml) Sodium Heparin vacutainer labeled as **Se.**
2. Fill tiger top (6ml) SST vacutainer labeled as **PSA.**

BLOOD PROCESSING

*** FOR OPTIMAL RESULTS, IT IS SUGGESTED THAT THE SST VACUTAINERS SIT FOR 20MIN WITH PATIENT'S WHOLE BLOOD BEFORE THEY ARE SPUN DOWN. IN ADDITION, PLEASE INVERT THE BLUE TOP SODIUM HEPARIN VACUTAINER 8-10 TIMES AFTER THEY ARE FILLED WITH WHOLE BLOOD. ***

1. Spin down tiger top SST vacutainer labeled as **PSA**.
2. Using a transfer pipet, transfer serum from SST vacutainer labeled **PSA** into the purple top aliquot tube labeled as **PSA.**

END RESULTS FOR MAILING

1. 1 navy blue top Sodium Heparin vacutainer labeled as **Se** with approximately 8ml of whole blood.
2. 1 purple top aliquot tube labeled as **PSA** with 1ml of serum.

We realize that variability in patient blood draw volume will occur. Please draw blood in the specified order. Thank you.

P:\SeLECT Study\laboratoy\OffSite Blood Draw\Select_Blood Draw Protocol #1.doc

PROCEDURE FOR DRAWING, PROCESSING, AND MAILING PLASMA AND BLOOD SPECIMENS (Select A.E.)

Enclosed are the following supplies:

i) One blue top sodium heparin vacutainer tube (8ml).
ii) One tiger top SST vacutainer tubes (6ml).
iii) Plasma/Serum storage aliquots (3).
iv) Sample number labels.
v) Transfer pipet.
vi) Absorbent paper.
vii) Refrigerant pack.
viii) Foam packing.
ix) Styrofoam shipping box.
x) FedEx diagnostic specimen envelope.
xi) FedEx completed packing slip and mailing sleeve.
xii) White cardboard shipping box.

Directions for drawing and shipping blood sample:

1. Please refer to the WHITE **Off-Site Blood Draw Protocol** for drawing and processing procedures.

2. Place all filled vacutainer tubes and specified aliquot tubes inside the plastic bag with the empty aliquot tubes and absorbent paper. Put this bag inside the styrofoam box cushioned between the foam and refrigerant pack.

3. **COMPLETE THE YELLOW FORM** and place this form in the box on top of the foam.

4. **After closing the styrofoam sample box,** place it into the cardboard box and tape securely.

5. **Place cardboard box** inside the large plastic FedEx diagnostic specimen bag, following the instructions on the bag.

6. **Put the FedEx shipping label** inside the mailing sleeve and stick on the specimen bag in the marked area.

7. Mail sample package **on the day of the blood draw** to the Tucson Coordinating Center using Federal Express. To ship overnight, please **call Federal Express at 1-800-238-5355--PLEASE DO NOT DRAW OR MAIL ON A FRIDAY**.

8. **Call Brian Hartman toll-free at 1-800-243-6519, ext. 32** so that he can expect to receive the sample the following day.

If you have **ANY** questions, please call Brian Hartman, Laboratory Technician, toll-free at 1-800-243-6519, ext. 32.

THANK YOU VERY MUCH FOR YOUR ASSISTANCE WITH THIS IMPORTANT CANCER PREVENTION PROJECT.

PROCEDURE FOR DRAWING, PROCESSING, AND MAILING PLASMA AND BLOOD SPECIMENS (Select V1)

Enclosed are the following supplies:

i) One blue top sodium heparin vacutainer tube (7ml).
ii) Two tiger top SST vacutainer tube (9.5ml).
iii) Plasma/Serum storage aliquots (8).
iv) Sample number labels.
v) Transfer pipet.
vii) Absorbent paper.
viii) Refrigerant pack.
ix) Foam packing.
x) Styrofoam shipping box.
xi) FedEx diagnostic specimen envelope.
xii) FedEx completed packing slip and mailing sleeve.
xiii) White cardboard shipping box.

Directions for drawing and shipping blood sample:

1. Please refer to the WHITE **Off-Site Blood Draw Protocol** form for drawing and processing procedures.

2. **Place** all filled vacutainer tubes and specified aliquot tubes inside the plastic bag with the empty aliquot tubes and absorbent paper. Put this bag inside the styrofoam box cushioned between the foam and refrigerant pack.

3. **COMPLETE THE YELLOW FORM** and place this form in the box on top of the foam.

4. **After closing the styrofoam sample box,** place it into the cardboard box and tape securely.

5. **Place cardboard box** inside the large plastic FedEx diagnostic specimen bag, following the instructions on the bag.

6. **Put the FedEx shipping label** inside the mailing sleeve and stick on the specimen bag in the marked area.

7. Mail sample package **on the day of the blood draw** to the Tucson Coordinating Center using Federal Express. To ship overnight, please **call Federal Express at 1-800-238-5355--PLEASE DO NOT DRAW OR MAIL ON A FRIDAY**.

8. **Call Brian Hartman toll-free at 1-800-243-6519, ext. 32** so that he can expect to receive the sample the following day.

If you have **ANY** questions, please call Brian Hartman, Laboratory Technician, toll-free at 1-800-243-6519, ext 32.

THANK YOU VERY MUCH FOR YOUR ASSISTANCE WITH THIS IMPORTANT CANCER PREVENTION PROJECT.

PROCEDURE FOR DRAWING, PROCESSING, AND MAILING PLASMA AND BLOOD SPECIMENS (Select V2)

Enclosed are the following supplies:

i) One blue top sodium heparin vacutainer tube (8ml).
ii) One tiger top SST vacutainer tubes (9.5ml).
iii) Plasma/Serum storage aliquots (5).
iv) Sample number labels.
v) Transfer pipet.
vi) Absorbent paper.
vii) Refrigerant pack.
viii) Foam packing.
ix) Styrofoam shipping box.
x) FedEx diagnostic specimen envelope.
xi) FedEx completed packing slip and mailing sleeve.
xii) White cardboard shipping box.

Directions for drawing and shipping blood sample:

1. Please refer to the WHITE **Off-Site Blood Draw Protocol** for drawing and processing procedures.

2. Place all filled vacutainer tubes and specified aliquot tubes inside the plastic bag with the empty aliquot tubes and absorbent paper. Put this bag inside the styrofoam box cushioned between the foam and refrigerant pack.

3. **COMPLETE THE YELLOW FORM** and place this form in the box on top of the foam.

4. **After closing the styrofoam sample box,** place it into the cardboard box and tape securely.

5. **Place cardboard box** inside the large plastic FedEx diagnostic specimen bag, following the instructions on the bag.

6. **Put the FedEx shipping label** inside the mailing sleeve and stick on the specimen bag in the marked area.

7. Mail sample package **on the day of the blood draw** to the Tucson Coordinating Center using Federal Express. To ship overnight, please **call Federal Express at 1-800-238-5355--PLEASE DO NOT DRAW OR MAIL ON A FRIDAY.**

8. **Call Brian Hartman toll-free at 1-800-243-6519, ext. 32** so that he can expect to receive the sample the following day.

If you have **ANY** questions, please call Brian Hartman, Laboratory Technician, toll-free at 1-800-243-6519, ext. 32.

THANK YOU VERY MUCH FOR YOUR ASSISTANCE WITH THIS IMPORTANT CANCER PREVENTION PROJECT.

PROCEDURE FOR DRAWING, PROCESSING, AND MAILING PLASMA AND BLOOD SPECIMENS (Select V3)

Enclosed are the following supplies:

i) One blue top sodium heparin vacutainer tube (8ml).
ii) Two tiger top SST vacutainer tubes (6ml).
iii) Plasma/Serum storage aliquots (6).
iv) Sample number labels.
v) Transfer pipet.
vi) Absorbent paper.
vii) Refrigerant pack.
viii) Foam packing.
ix) Styrofoam shipping box.
x) FedEx diagnostic specimen envelope.
xi) FedEx completed packing slip and mailing sleeve.
xii) White cardboard shipping box.

Directions for drawing and shipping blood sample:

1. Please refer to the WHITE **Off-Site Blood Draw Protocol** for drawing and processing procedures.

2. Place all filled vacutainer tubes and specified aliquot tubes inside the plastic bag with the empty aliquot tubes and absorbent paper. Put this bag inside the styrofoam box cushioned between the foam and refrigerant pack.

3. **COMPLETE THE YELLOW FORM** and place this form in the box on top of the foam.

4. **After closing the styrofoam sample box,** place it into the cardboard box and tape securely.

5. **Place cardboard box** inside the large plastic FedEx diagnostic specimen bag, following the instructions on the bag.

6. **Put the FedEx shipping label** inside the mailing sleeve and stick on the specimen bag in the marked area.

7. Mail sample package **on the day of the blood draw** to the Tucson Coordinating Center using Federal Express. To ship overnight, please **call Federal Express at 1-800-238-5355--PLEASE DO NOT DRAW OR MAIL ON A FRIDAY.**

8. **Call Brian Hartman toll-free at 1-800-243-6519, ext. 32** so that he can expect to receive the sample the following day.

If you have **ANY** questions, please call Brian Hartman, Laboratory Technician, toll-free at 1-800-243-6519, ext. 32.

THANK YOU VERY MUCH FOR YOUR ASSISTANCE WITH THIS IMPORTANT CANCER PREVENTION PROJECT.

P:\SeLECT Study\laboratoy\Laboratory Forms(blue)\Draw_FedEx Instruc2.doc

PROCEDURE FOR DRAWING, PROCESSING, AND MAILING PLASMA AND BLOOD SPECIMENS (Select V4)

Enclosed are the following supplies:

i) One blue top sodium heparin vacutainer tube (8ml).
ii) One tiger top SST vacutainer tubes (9.5ml).
iii) Plasma/Serum storage aliquots.
iv) Sample number labels.
v) Transfer pipet.
vi) Absorbent paper.
vii) Refrigerant pack.
viii) Foam packing.
ix) Styrofoam shipping box.
x) FedEx diagnostic specimen envelope.
xi) FedEx completed packing slip and mailing sleeve.
xii) White cardboard shipping box.

Directions for drawing and shipping blood sample:

1. Please refer to the WHITE **Off-Site Blood Draw Protocol** for drawing and processing procedures.

2. Place all filled vacutainer tubes and specified aliquot tubes inside the plastic bag with the empty aliquot tubes and absorbent paper. Put this bag inside the styrofoam box cushioned between the foam and refrigerant pack.

3. **COMPLETE THE YELLOW FORM** and place this form in the box on top of the foam.

4. **After closing the styrofoam sample box,** place it into the cardboard box and tape securely.

5. **Place cardboard box** inside the large plastic FedEx diagnostic specimen bag, following the instructions on the bag.

6. **Put the FedEx shipping label** inside the mailing sleeve and stick on the specimen bag in the marked area.

7. Mail sample package **on the day of the blood draw** to the Tucson Coordinating Center using Federal Express. To ship overnight, please **call Federal Express at 1-800-238-5355--PLEASE DO NOT DRAW OR MAIL ON A FRIDAY.**

8. **Call Brian Hartman toll-free at 1-800-243-6519, ext. 32** so that he can expect to receive the sample the following day.

If you have **ANY** questions, please call Brian Hartman, Laboratory Technician, toll-free at 1-800-243-6519, ext. 32.

THANK YOU VERY MUCH FOR YOUR ASSISTANCE WITH THIS IMPORTANT CANCER PREVENTION PROJECT.

PROCEDURE FOR DRAWING, PROCESSING, AND MAILING PLASMA AND BLOOD SPECIMENS (Select V5)

Enclosed are the following supplies:

i) One blue top sodium heparin vacutainer tube (8ml).
ii) Two tiger top SST vacutainer tubes (6ml).
iii) Plasma/Serum storage aliquots (6).
iv) Sample number labels.
v) Transfer pipet.
vi) Absorbent paper.
vii) Refrigerant pack.
viii) Foam packing.
ix) Styrofoam shipping box.
x) FedEx diagnostic specimen envelope.
xi) FedEx completed packing slip and mailing sleeve.
xii) White cardboard shipping box.

Directions for drawing and shipping blood sample:

1. Please refer to the WHITE **Off-Site Blood Draw Protocol** for drawing and processing procedures.

2. Place all filled vacutainer tubes and specified aliquot tubes inside the plastic bag with the empty aliquot tubes and absorbent paper. Put this bag inside the styrofoam box cushioned between the foam and refrigerant pack.

3. **COMPLETE THE YELLOW FORM** and place this form in the box on top of the foam.

4. **After closing the styrofoam sample box,** place it into the cardboard box and tape securely.

5. **Place cardboard box** inside the large plastic FedEx diagnostic specimen bag, following the instructions on the bag.

6. **Put the FedEx shipping label** inside the mailing sleeve and stick on the specimen bag in the marked area.

7. Mail sample package **on the day of the blood draw** to the Tucson Coordinating Center using Federal Express. To ship overnight, please **call Federal Express at 1-800-238-5355--PLEASE DO NOT DRAW OR MAIL ON A FRIDAY**.

8. **Call Brian Hartman toll-free at 1-800-243-6519, ext. 32** so that he can expect to receive the sample the following day.

If you have **ANY** questions, please call Brian Hartman, Laboratory Technician, toll-free at 1-800-243-6519, ext. 32.

THANK YOU VERY MUCH FOR YOUR ASSISTANCE WITH THIS IMPORTANT CANCER PREVENTION PROJECT.

PROCEDURE FOR DRAWING, PROCESSING, AND MAILING PLASMA AND BLOOD SPECIMENS (Select V6)

Enclosed are the following supplies:

i) One blue top sodium heparin vacutainer tube (8ml).
ii) One tiger top SST vacutainer tubes (9.5ml).
iii) Plasma/Serum storage aliquots.
iv) Sample number labels.
v) Transfer pipet.
vi) Absorbent paper.
vii) Refrigerant pack.
viii) Foam packing.
ix) Styrofoam shipping box.
x) FedEx diagnostic specimen envelope.
xi) FedEx completed packing slip and mailing sleeve.
xii) White cardboard shipping box.

Directions for drawing and shipping blood sample:

1. Please refer to the WHITE **Off-Site Blood Draw Protocol** for drawing and processing procedures.

2. Place all filled vacutainer tubes and specified aliquot tubes inside the plastic bag with the empty aliquot tubes and absorbent paper. Put this bag inside the styrofoam box cushioned between the foam and refrigerant pack.

3. **COMPLETE THE YELLOW FORM** and place this form in the box on top of the foam.

4. **After closing the styrofoam sample box,** place it into the cardboard box and tape securely.

5. **Place cardboard box** inside the large plastic FedEx diagnostic specimen bag, following the instructions on the bag.

6. **Put the FedEx shipping label** inside the mailing sleeve and stick on the specimen bag in the marked area.

7. Mail sample package **on the day of the blood draw** to the Tucson Coordinating Center using Federal Express. To ship overnight, please **call Federal Express at 1-800-238-5355--PLEASE DO NOT DRAW OR MAIL ON A FRIDAY**.

8. **Call Brian Hartman toll-free at 1-800-243-6519, ext. 32** so that he can expect to receive the sample the following day.

If you have **ANY** questions, please call Brian Hartman, Laboratory Technician, toll-free at 1-800-243-6519, ext. 32.

THANK YOU VERY MUCH FOR YOUR ASSISTANCE WITH THIS IMPORTANT CANCER PREVENTION PROJECT.

Select Blood Processing Instructions (Kit 1)

A. Kit Should Contain:

1 Sodium Heparin Vacutainer -8ml (Navy Blue Top)
2 SST Serum Separator Vacutainer-9.5ml (Tiger Top)

B. Directions for Processing:

Sodium Heparin Tubes

1. Spin down the Sodium Heparin tube in centrifuge for 7-10 minutes.
2. Fill the two aliquot tubes labeled Se I and Se2 with plasma from this tube.

SST Tubes

1. Spin down both SST tubes in centrifuge for 7-10 minutes.
2. Fill the PSA aliquot tube with serum from the 9.5ml SST tube. This aliquot tube has a purple top.
3. Fill the Lycopene aliquot tube with serum from the same 9.5ml SST tube.
4. With the remaining serum fill the aliquot tube labeled as Vit. E. This aliquot tube has a white stripe and antioxidant inside.
5. Fill the CMP aliquot tube with the serum from the other 9.5ml SST tube.
6. With the remaining serum fill the two aliquots labeled as Chrom-A.

C. Directions for Storing Aliquot Tubes:

1. Place Se I aliquot tube into the box marked Cornell Se, found in Freezer B
2. Place Se2 aliquot tube into the box labeled To be Entered, located in Freezer B.
3. Place PSA aliquot tube into the box labeled PSA, located in Freezer B.
4. Place Chrom-A, Lycopene, and Vit. E aliquot tubes into the box labeled To Be Entered.

D. Directions for Transporting Samples to SmithKline Beecham:

1. Write participants' last name, first name and draw date on a blank label and affix it over the SS label on the CMP aliquot.
2. Place the CMP aliquot into a SKB specimen bag for SmithKline.
3. Fill out SmithKline: *Select Test* form (located in SELECT filing cabinet, drawer 2).
4. Print patient's name, DOB, and sex in appropriate boxes.
5. Check "account" under the section that says Bill To.
6. Complete the date collected and time section.
7. Mark **COMP METABOLIC PANEL** (34389-3).
8. Mark ALT (SGPT) (823-10).
9. If there are any questions, refer to sample form in SELECT filing cabinet, drawer 2).
10. Call courier 332-8264? Drop off SST aliquots at front window.

E. Directions for Incoming Participant's Urologist of Their Lab Results

1. Photocopy laboratory results from form from SmithKline.
2. Send photocopied results along with cover letter located in P:\SeLECT Study\Letters\letter to Dr..doc to patient's Urologist.

Select Blood Processing Instructions (Kit 2)

A. Kit Should Contain:

1 Sodium Heparin Vacutainer -8ml (Navy Blue Top)
1 SST Serum Separator Vacutainers-9.5ml (Tiger Top)

B. Directions for Processing:

Sodium Heparin Tubes

1. Spin down the Sodium Heparin tube in centrifuge for 7-10 minutes.

2. Fill the two aliquot tubes labeled Se I and Se2 with plasma from this tube.

SST Tubes

1. Spin down both SST tubes in centrifuge for 7-10 minutes.

2. Fill the PSA aliquot with serum from one of the SST tubes. This aliquot tube has a purple top.

3. Fill the Chrom-A aliquot tubes with serum from the same 9.5ml SST tube.

C. Directions for Storing Aliquot Tubes:

1. Place Se I aliquot tube into the box marked Cornell Se, found in Freezer B

2. Place Se2 aliquot tube into the box labeled To be Entered, located in Freezer B.

3. Place PSA aliquot tube into the box labeled PSA, located in Freezer B.

4. Place Chrom-A aliquot tube into the box labeled To Be Entered.

SeLECT Blood Processing Instructions (Kit 3)

A. Kit Should Contain:

1 Sodium Heparin Vacutainer 8ml (Navy Blue Top)
2 SST Serum Separator Vacutainer 6ml (Tiger Top)

B. Directions for Processing:

Sodium Heparin Tubes

1. Spin down the Sodium Heparin tube in centrifuge for 7-10 minutes.
2. Fill the two aliquot tubes labeled Se l and Se 2 with plasma from this tube.

SST Tubes

1. Spin down both SST tubes in centrifuge for 7-10 minutes.
2. Fill PSA aliquot tube with serum from the 6ml SST Tube.
3. Fill the CMP aliquout with the remaining serum from the same 6ml SST Tube.
4. With the other 6ml SST Tube fill the aliquots labeled as Chrom-A.

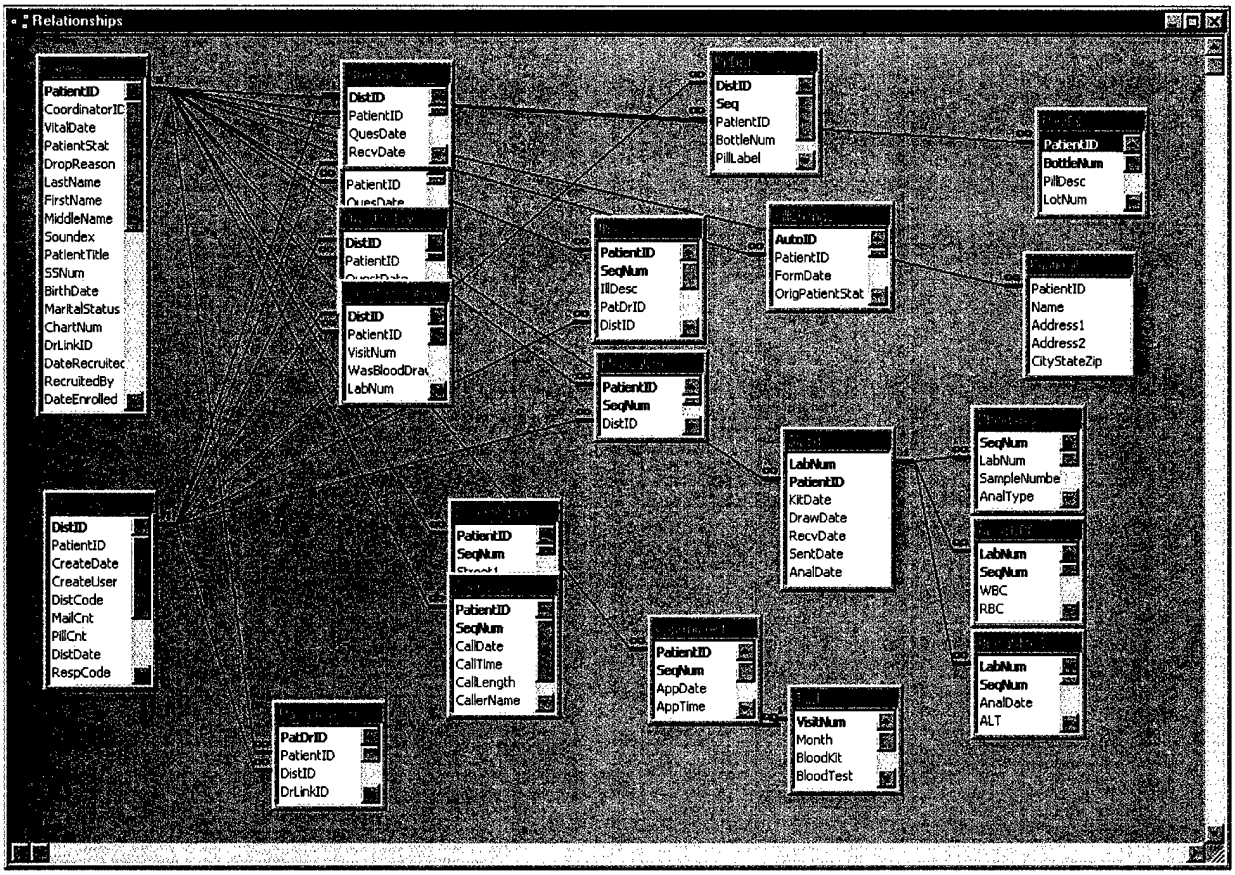
C. Directions for Storing Aliquot Tubes:

1. Place Se I aliquot tube into the box marked Cornell Se, found in Freezer B
2. Place Se2 aliquot tube into the box labeled To Be Entered, located in Freezer B.
3. Place PSA aliquot tube into the box labeled PSA, located in Freezer B.
4. Place the CMP aliquot tube into the box labeled To Be Entered, located in Freezer B.
5. Place the two Chrom-A aliquot tubes into the box labeled To Be Entered, located in Freezer B.

SElect Study
Computer Program Interface.

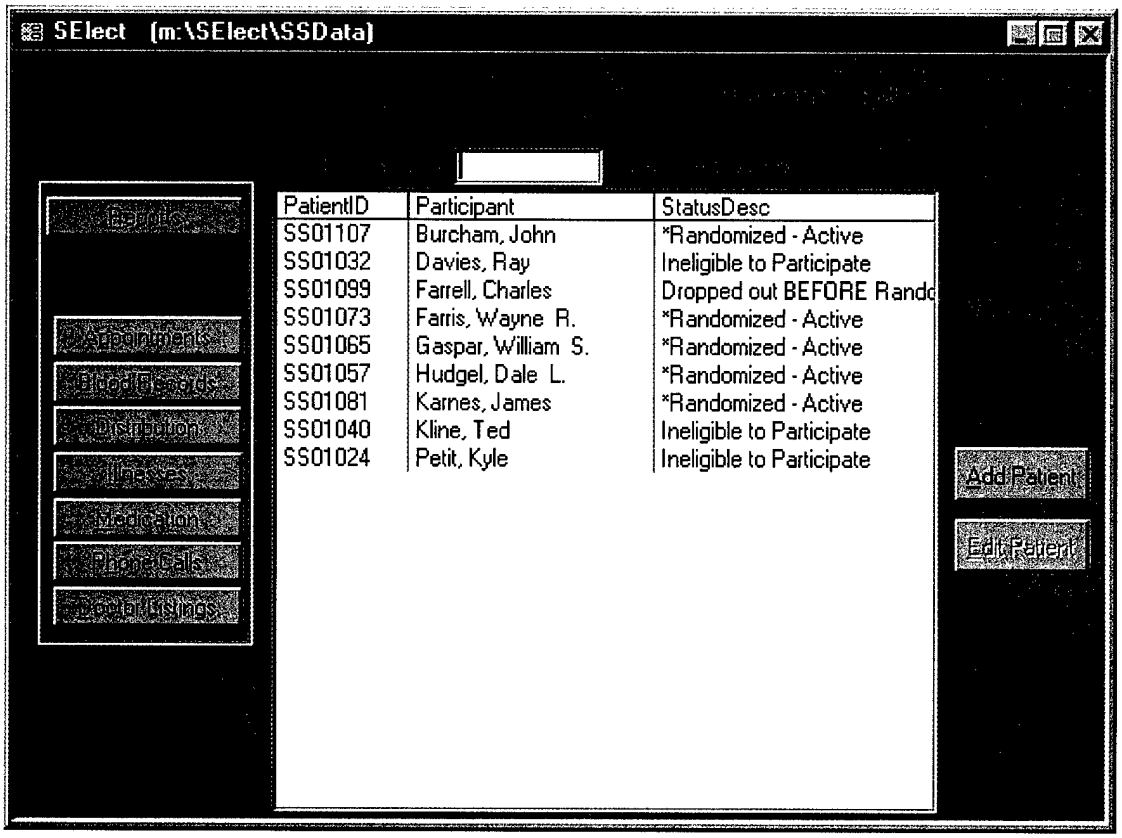
The following are screen images of what the computer program looks like. Not all screens are displayed and only represent a portion of what is used to run the SElect Study. There are many functions and capabilities this software has that is not represented here. For example, anything from the randomization process, to the assignment of participant IDs, the processing of bloods, to validating information already entered.

The image below represents most to the tables used in the trial (excludes standard lookup tables and other external tables used in all trials). The focus that needs to be shown is everything relies on two main tables – (1) the Patient table in the top left corner, and (2) the distribution table below that. This relational database structure is keyed to keeping all reference integrity based upon the unique PatientID field. All program coding automatically keeps the data intact. No manually entered PatientIDs is required. The Distribution table is used to track every item that goes out of the coordinating center to participants. More of this mentioned below.

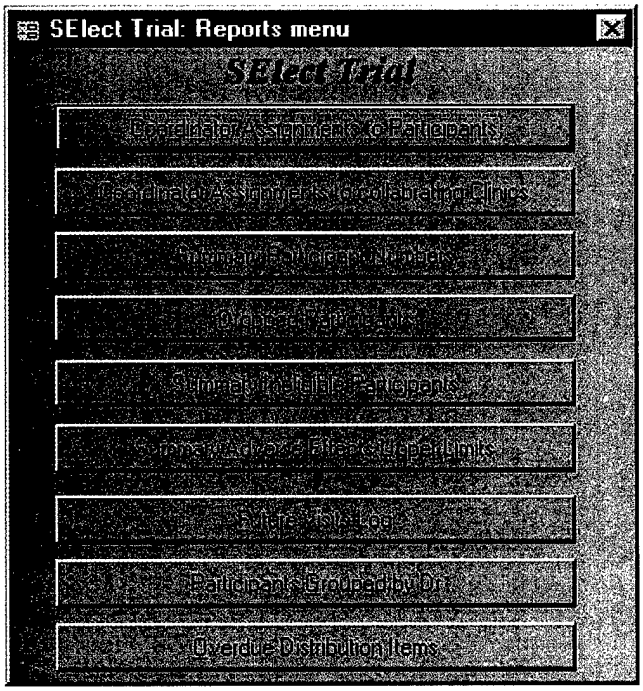


The first screen the coordinator sees is the main menu stating what program they are using. Color-coding is used to visually show the coordinator which trial they are working with (cyan background). The menu items on the left represent the viewing of the data as a whole. The data seen from these options are not specific to individual participants but to the whole trial.

The coordinator has the option of viewing and picking an existing participant from clicking on the name and choosing "Edit Patient", or just double-clicking on the name. For participants not yet in the computer, the coordinator chooses "Add Patient". The screens that follow are listed below.



The Reports button brings up the following screen to where the coordinator can display any number of reports to help run the trial. Other reports are created as needed.



Here is an example of a report showing a single page of which participants where assigned to the coordinator "PAW". This report allows the coordinator to quickly determine the status of each of their participants and take any actions necessary.

SElect Trial **Coordinator's Participants** ***Confidential*** *Page 3 of 3*

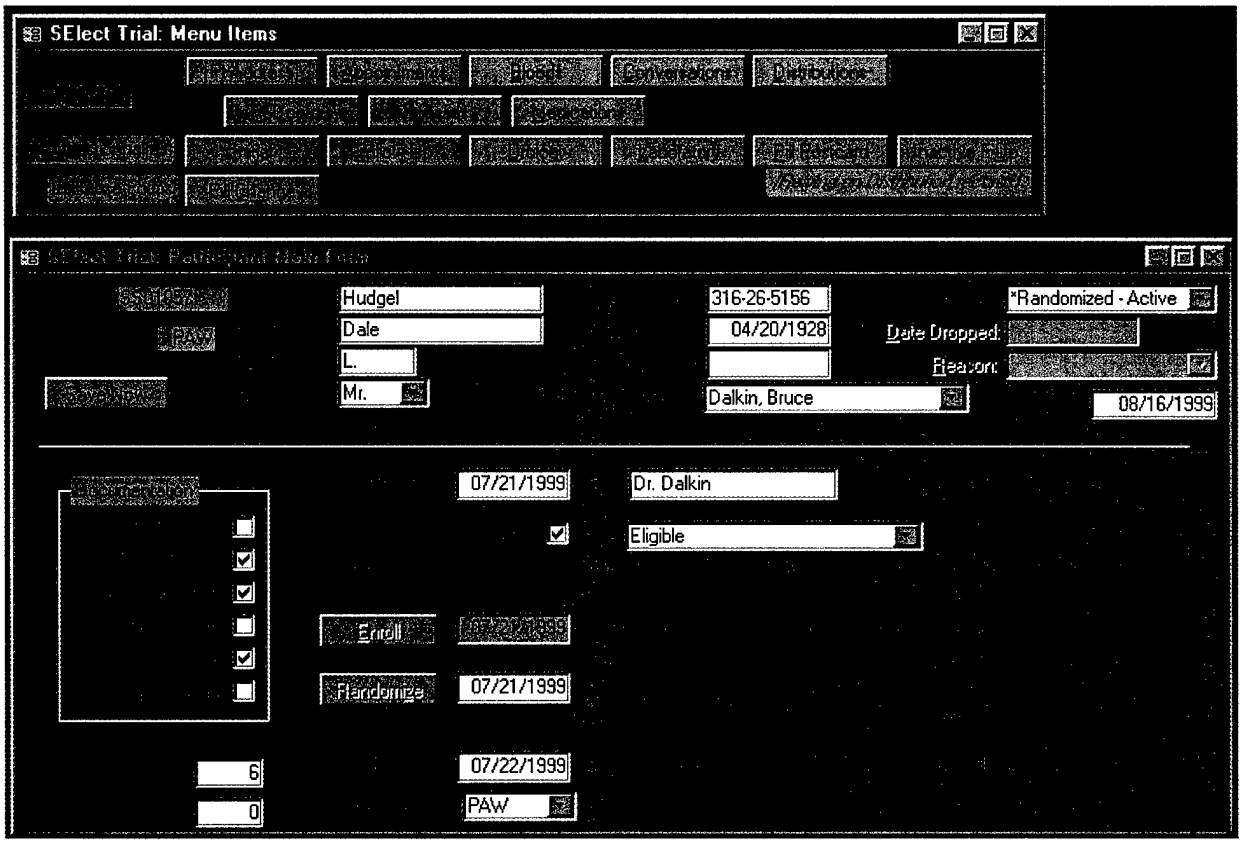
hursday, October 28, 1999 10:55:52 AM

ID	*Name*		*Recruited*	*Enrolled*	*Randomized*	*Took 1st Pill*	*Dropped*	
Coordinator	PAW							
SS01057	Hudgel	Dale	7/21/1999	7/21/1999	7/21/1999	7/22/1999		
SS01081	Karnes	James	8/16/1999	8/27/1999	9/6/1999	8/28/1999		
SS01040	Kline	Ted	6/29/1999	6/29/1999			7/1/1999	Didn't meet eligibility criteria
SS01024	Petit	Kyle	6/28/1999	6/29/1999			7/8/1999	Didn't meet eligibility criteria

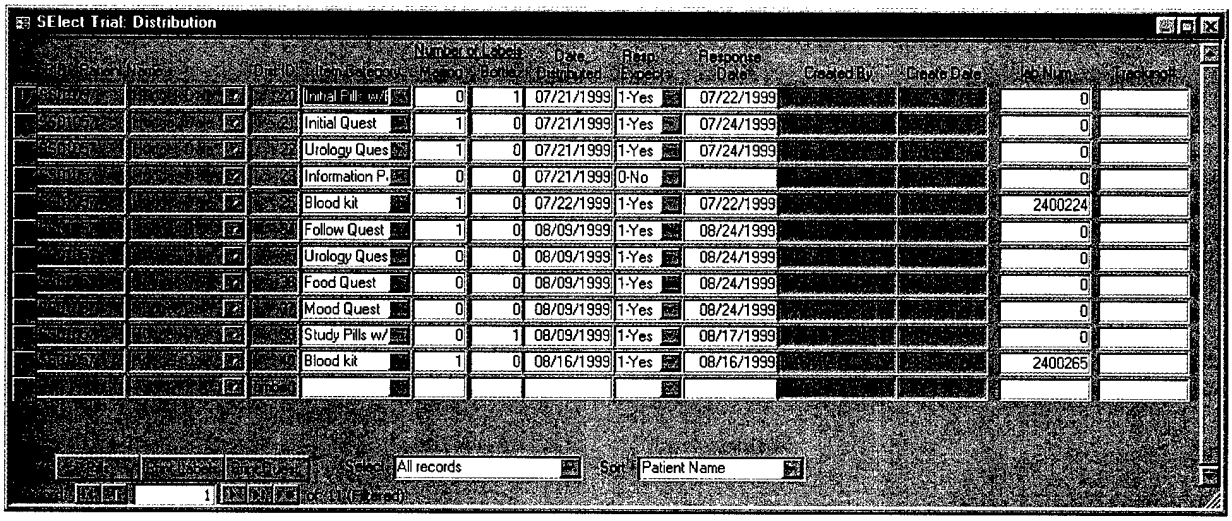
Total Number Recruited:	4	*Total Recruited then Dropped:*	0
Total Number Enrolled:	4	*Total Enrolled then Dropped:*	2
Total Number Randomized:	2	*Total Randomized then Dropped:*	0
Total Number took 1st Pills:	2	*Total Dropped Participants:*	2
		Total Recruited not yet Enrolled:	0
		Total Enrolled not yet Randomized:	0
		Total Pre-Randomized Active Participants:	0
		Total Randomized Active Participants:	2
		Total Active Participants:	2

Below is the starting point after choosing a participant. The main screen shows the status of the participant and all the latest and important information. The top portion is the menu system to bring up each individual form or questionnaire.

This screen is the first place the coordinator goes to enter data for a new participant or starts from for updating for existing participants. The PatientID is automatically generated with new participants and it includes a check-digit within the value. Even though the entry of a PatientID is rarely performed, the check-digit will prevent an accidentally entered value. Other critical fields (i.e. Lab number) also include a check-digit to prevent miss-assignment of data. Important dates are entered or shown from this screen, along with the status of each participant. If the participant meets eligibility, the randomization is performed on this screen.

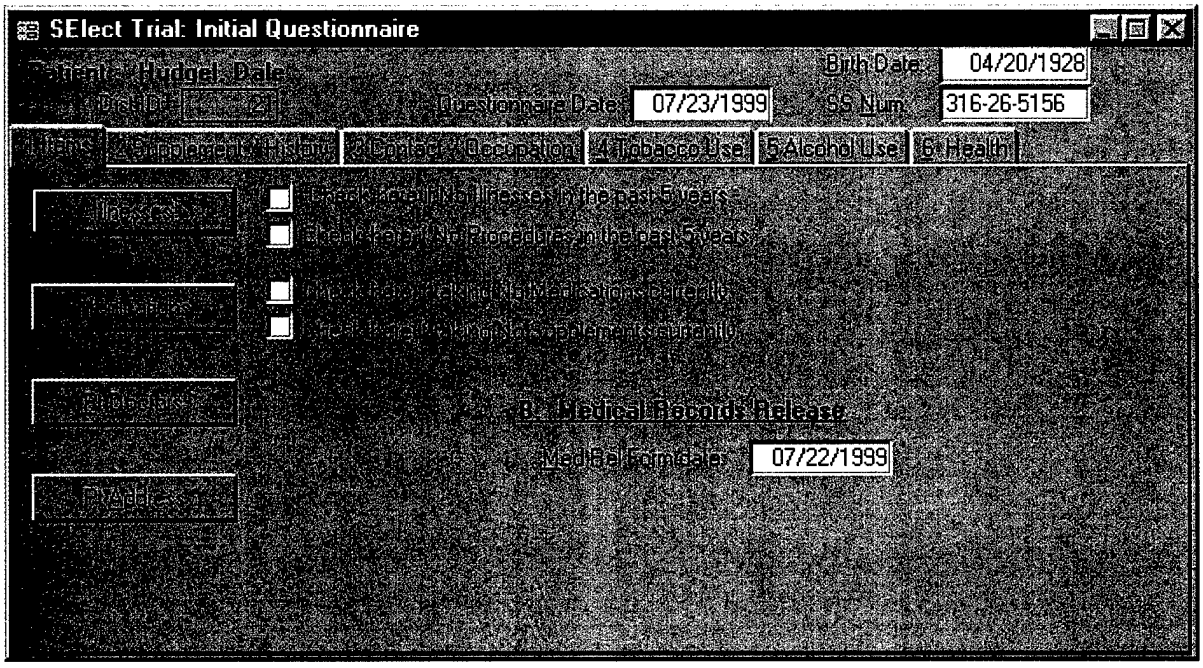


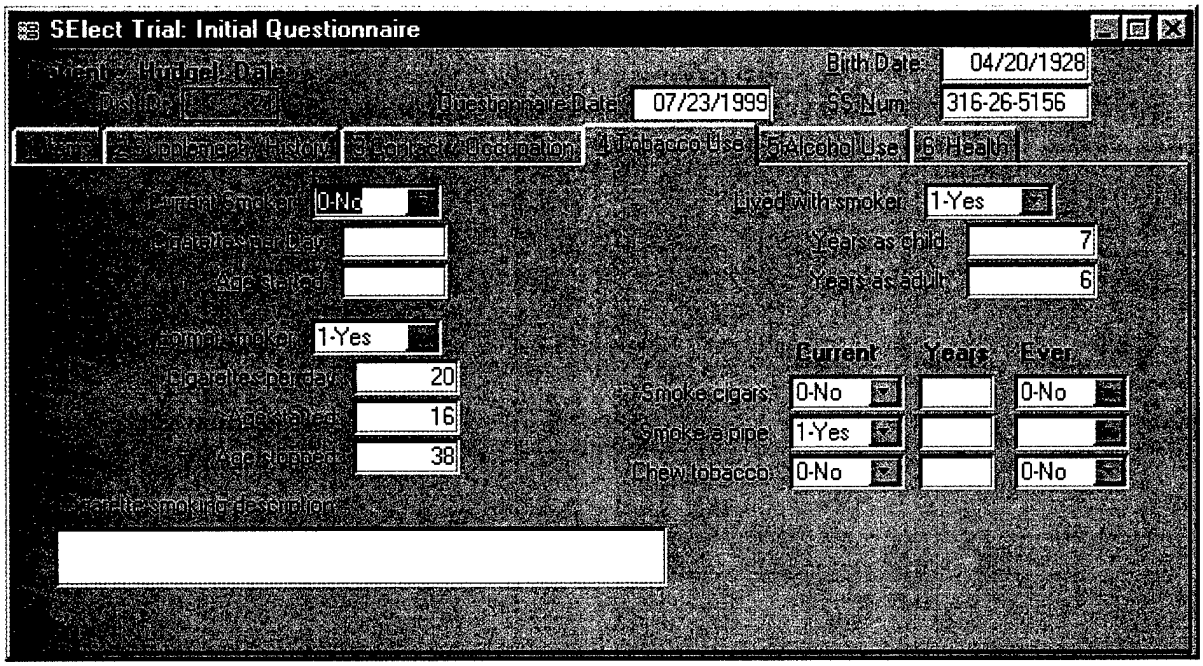
As discussed above, the Distribution table is the second most common table the coordinator uses. This table tracks everything that is sent out to the participant. If tracks what is sent out (and when) and what is expected back (and when). If we send something out, expect it back, and is not returned, this table and corresponding report will highlight what needs following up. As you can see from the screen shot, this participant has had several items sent to him on different dates: Pills, several different questionnaires, and blood kits.



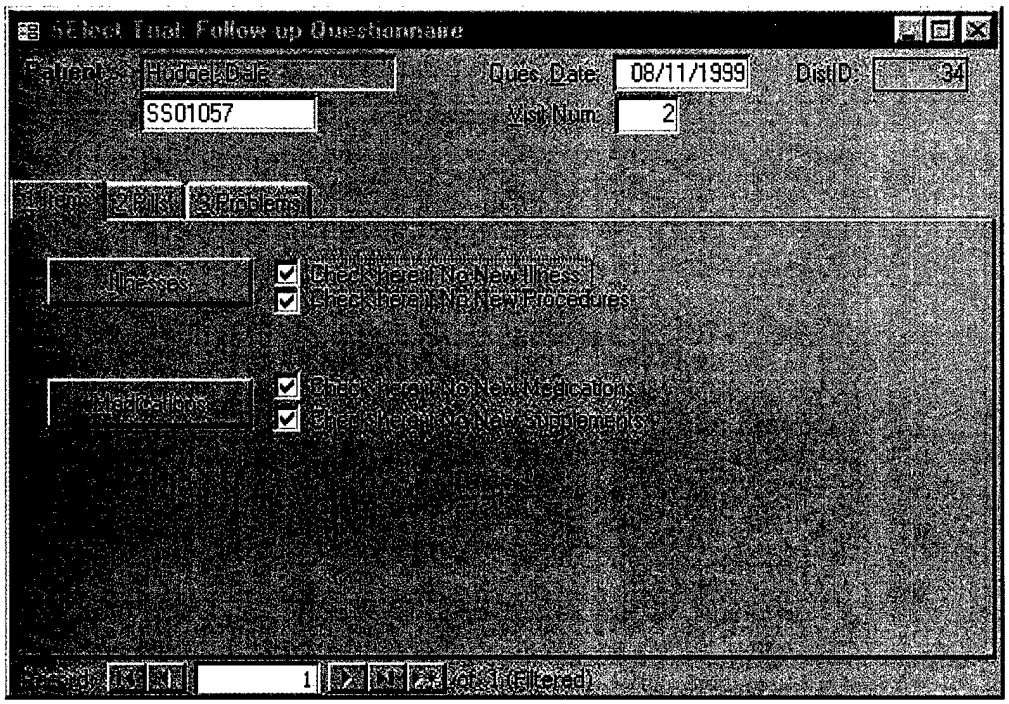
Here are some screen-shots of forms that represent the hardcopy questionnaires. The first questionnaire that the participant needs to complete is the Initial Questionnaire collecting baseline information.

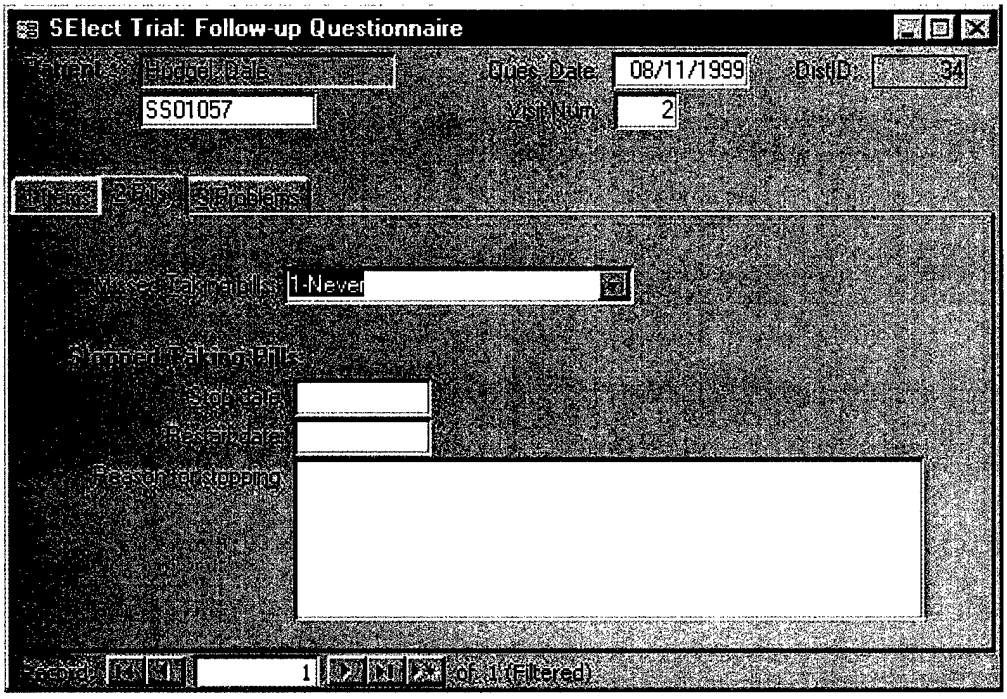
Most forms have access to the common input routine for Illness events and medication including east access to their doctors and address. This and the next screen-shot shows what is behind a tab that reflects each region or area on the hardcopy questionnaire.

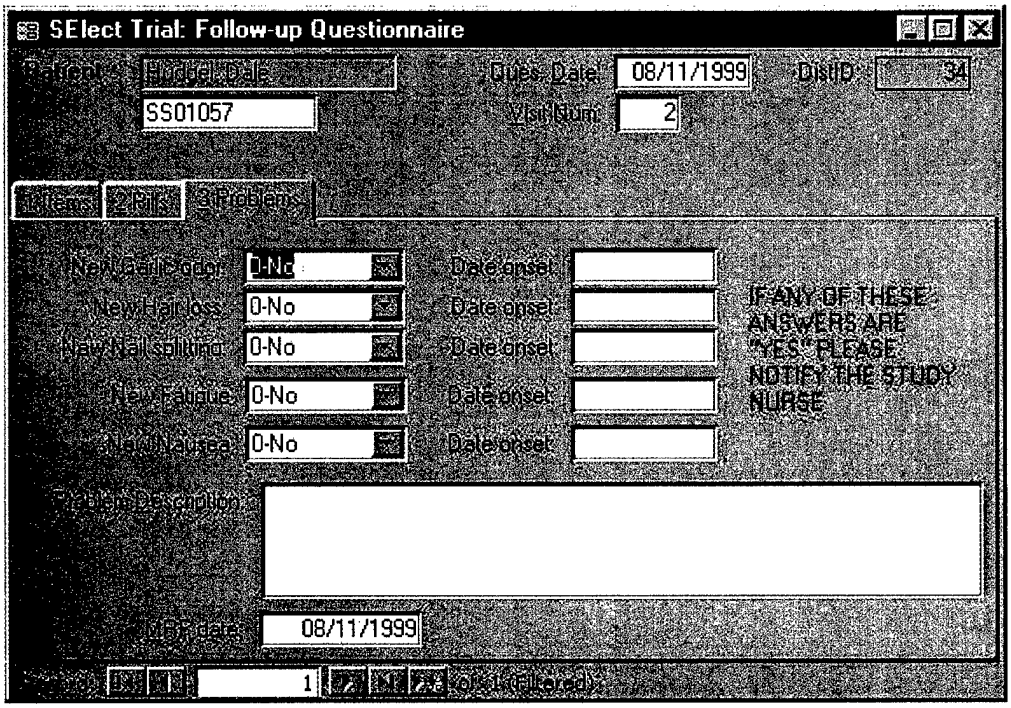




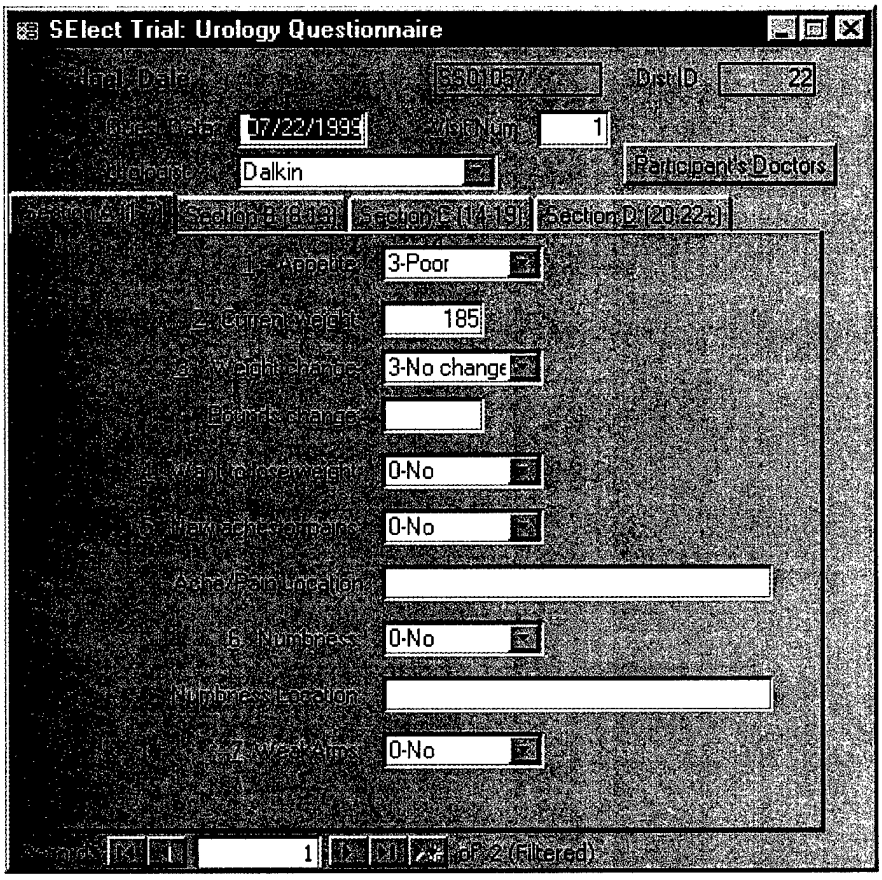
The following three screen-shots show each section of the follow-up questionnaire. Again, the first image allows for a common entry point for illness events and medication usage. The other images checks for compliance and any possible adverse effects.



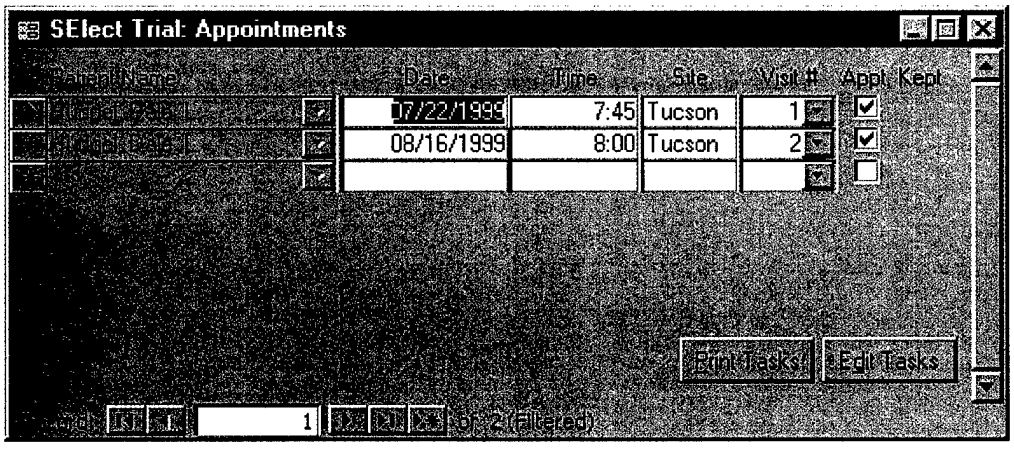


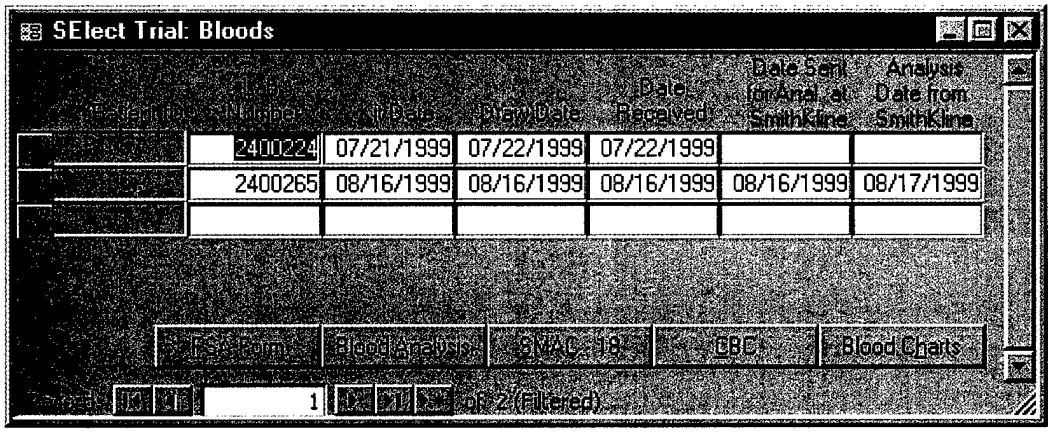


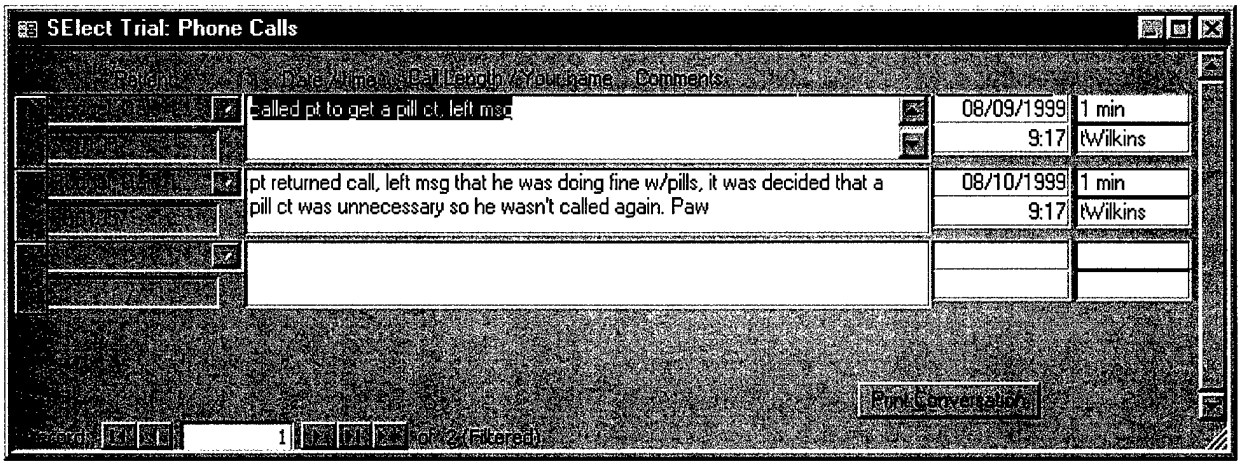
The Urology form has many questions relating to the prostate. Each tabbed section reflects a separate page on the hard-copy questionnaire.



The following are screen-shoots of other forms that are filled out through he course of trial and are self-explanatory.

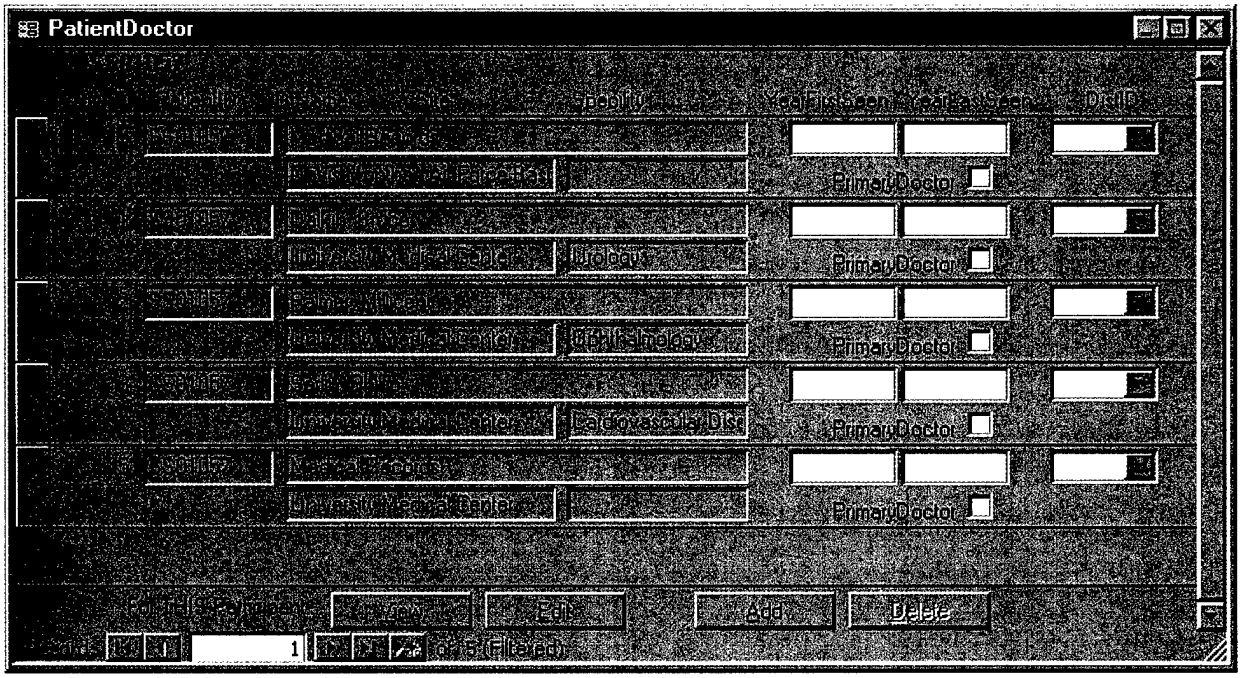






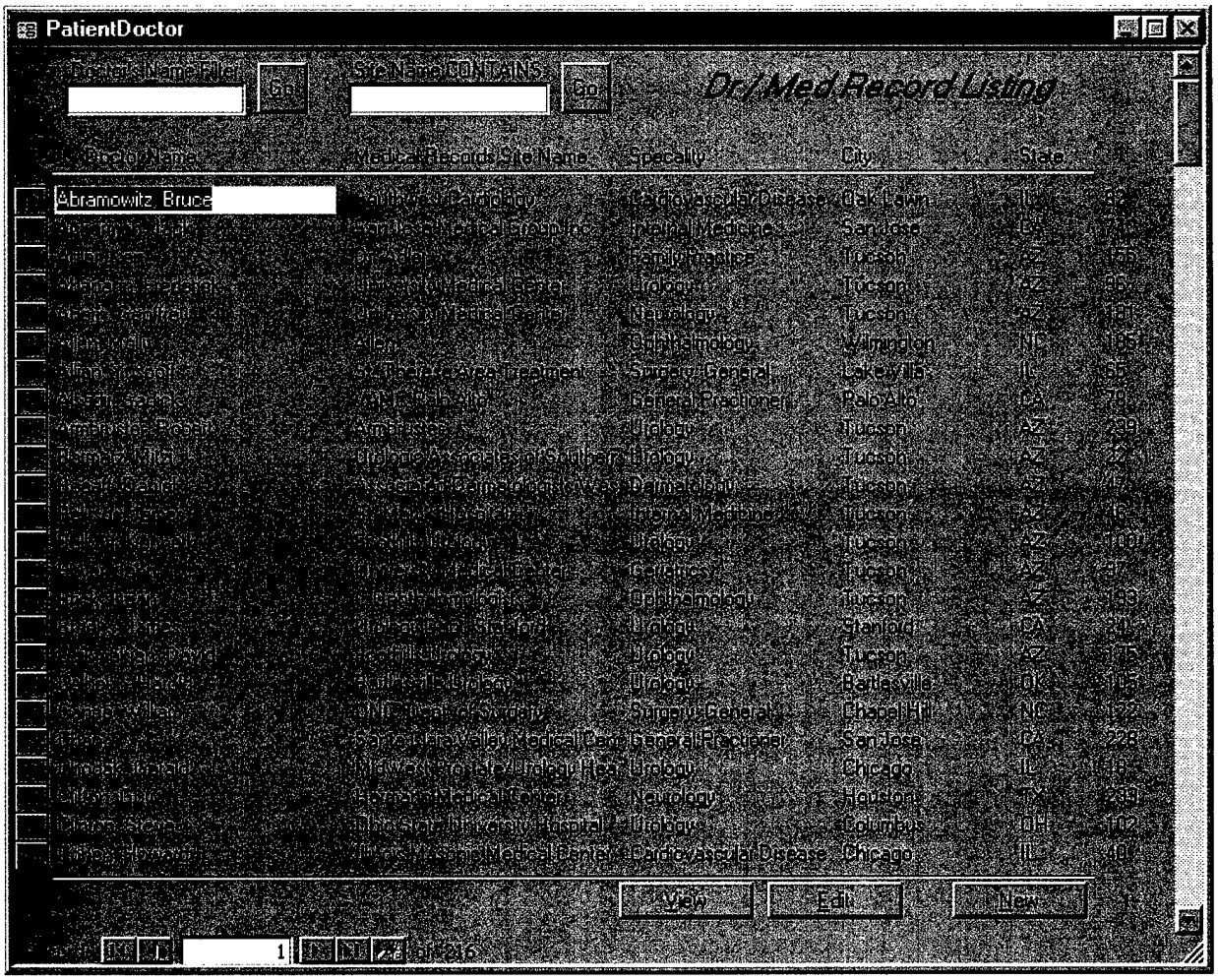
Due to the fact that all illness events are patient reported, we have a illness documentation system to confirm each report. For confirmation, we track all the doctors listed from each participant.

The screen below lists doctors for this one participant.

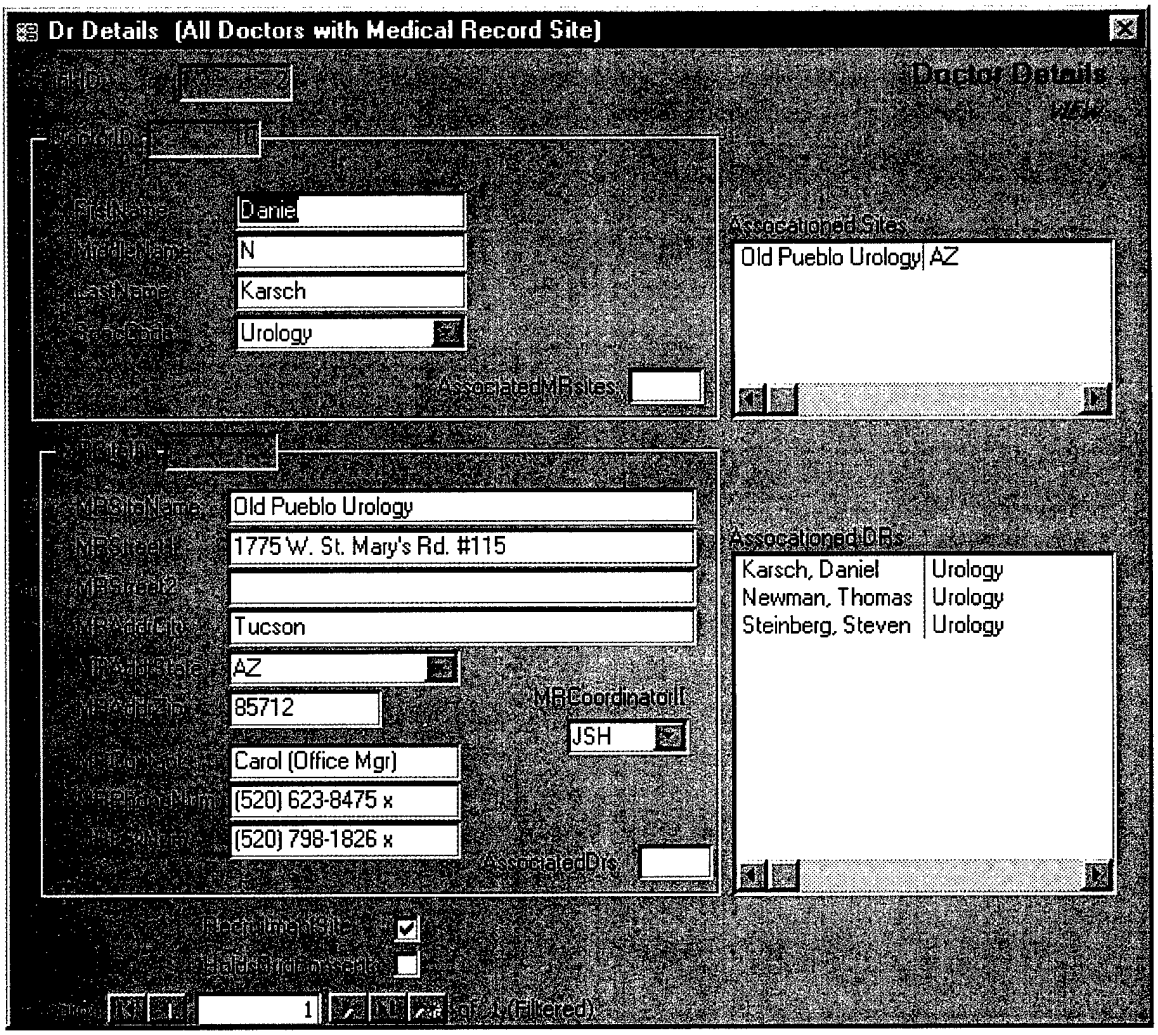


This is the screen showing all the current doctors that can be chosen from. A search criteria is used for either the doctor's name, or from the site name. Additional information is listed along side to help pinpoint the correct location.

The main concern for us, is the ability to obtain medical records for the participants. So we have recorded a doctor and the associated site where the medical records department address is located. The example below shows that this Medical Records Site has three collaborating doctors.



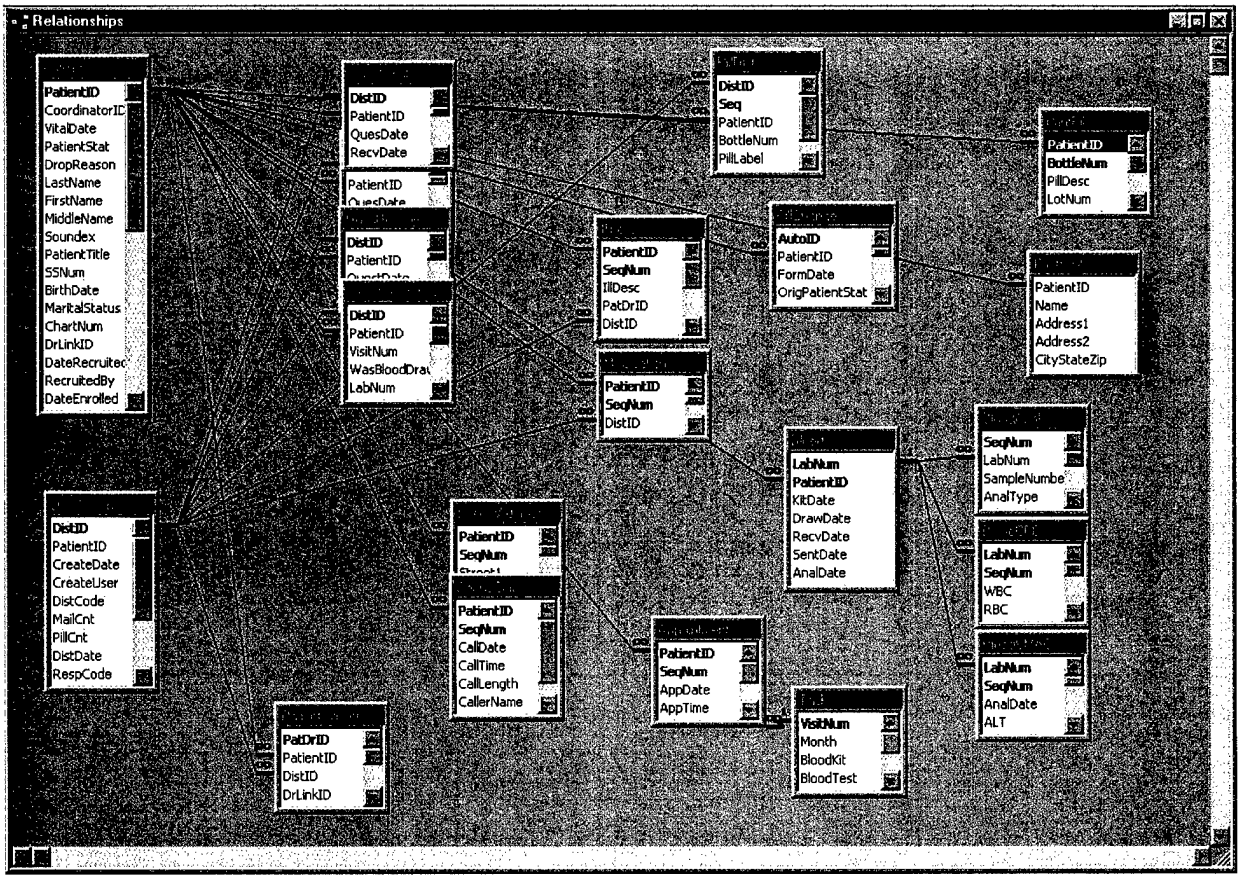
And this screen shows the ability to edit each doctor. The complexity is hidden that shows the many-to-many relationship between doctors and medical sites. A doctor can belong to many institutes and an institute has many doctors.



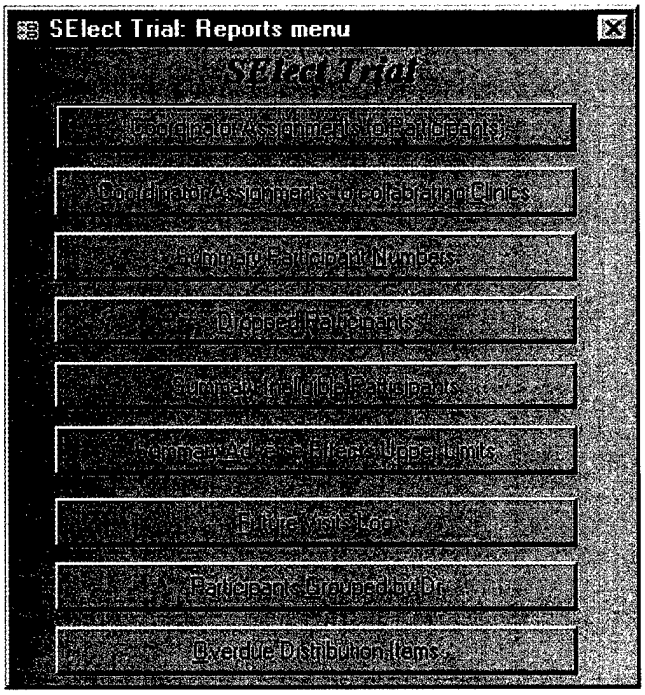
SElect Study
Computer Program Interface.

The following are screen images of what the computer program looks like. Not all screens are displayed and only represent a portion of what is used to run the SElect Study. There are many functions and capabilities this software has that is not represented here. For example, anything from the randomization process, to the assignment of participant IDs, the processing of bloods, to validating information already entered.

The image below represents most to the tables used in the trial (excludes standard lookup tables and other external tables used in all trials). The focus that needs to be shown is everything relies on two main tables – (1) the Patient table in the top left corner, and (2) the distribution table below that. This relational database structure is keyed to keeping all reference integrity based upon the unique PatientID field. All program coding automatically keeps the data intact. No manually entered PatientIDs is required. The Distribution table is used to track every item that goes out of the coordinating center to participants. More of this mentioned below.



The Reports button brings up the following screen to where the coordinator can display any number of reports to help run the trial. Other reports are created as needed.



Here is an example of a report showing a single page of which participants where assigned to the coordinator "PAW". This report allows the coordinator to quickly determine the status of each of their participants and take any actions necessary.

SElect Trial **Coordinator's Participants** *Confidential* *Page 3 of 3*

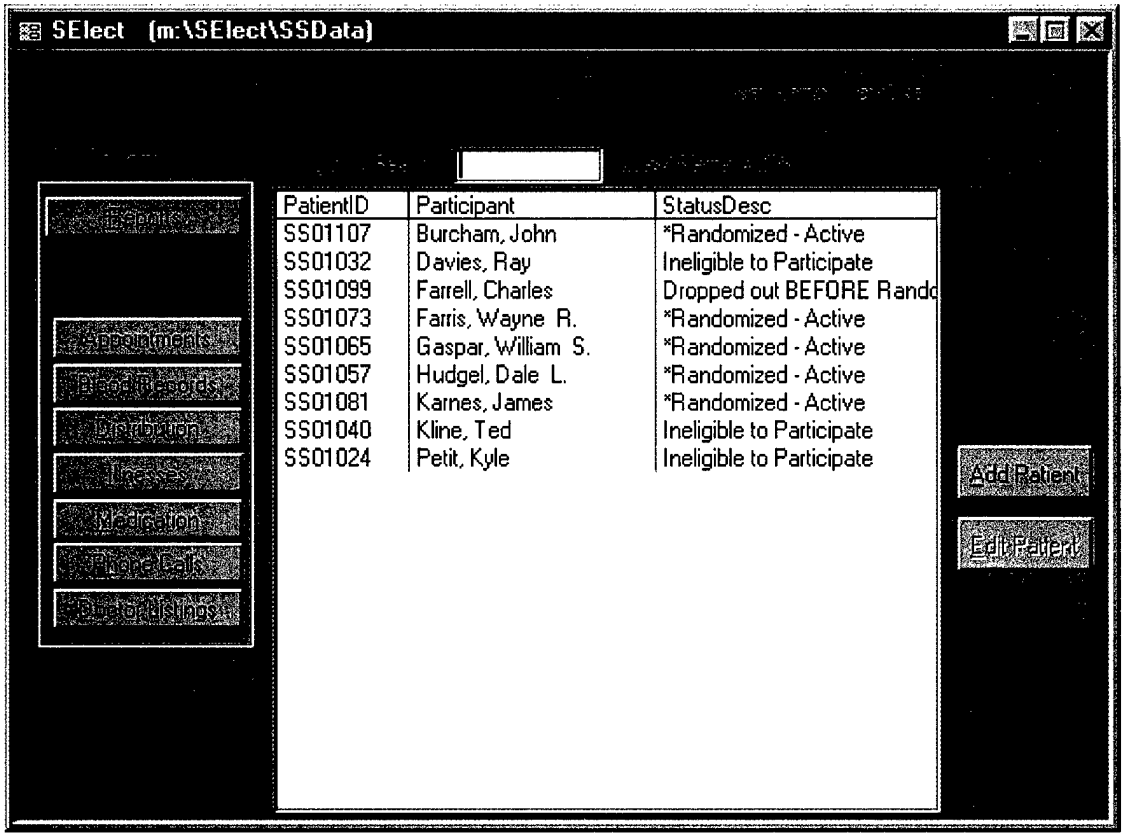
hursday, October 28, 1999 10:55:52 AM

ID	*Name*		*Recruited*	*Enrolled*	*Randomized*	*Took 1st Pill*	*Dropped*	
Coordinator	PAW							
SS01057	Hudgel	Dale	7/21/1999	7/21/1999	7/21/1999	7/22/1999		
SS01081	Karnes	James	8/18/1999	8/27/1999	9/6/1999	8/28/1999		
SS01040	Kline	Ted	6/29/1999	6/29/1999			7/1/1999	Didn't meet eligibility criteria
SS01024	Petit	Kyle	6/28/1999	6/29/1999			7/8/1999	Didn't meet eligibility criteria

Total Number Recruited:	4	*Total Recruited then Dropped:*	0
Total Number Enrolled:	4	*Total Enrolled then Dropped:*	2
Total Number Randomized:	2	*Total Randomized then Dropped:*	0
Total Number took 1st Pills:	2	*Total Dropped Participants:*	2
		Total Recruited not yet Enrolled:	0
		Total Enrolled not yet Randomized:	0
		Total Pre-Randomized Active Participants:	0
		Total Randomized Active Particiants:	2
		Total Active Participants:	2

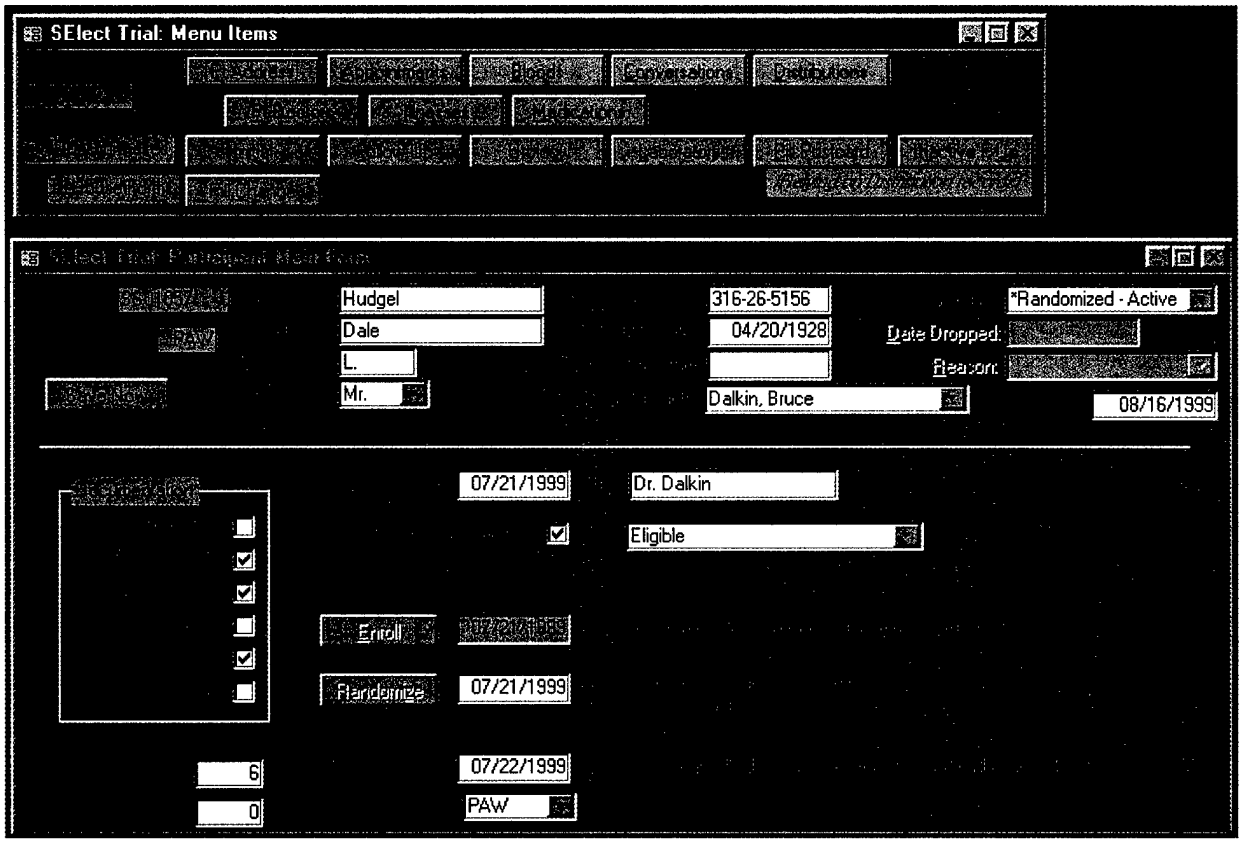
The first screen the coordinator sees is the main menu stating what program they are using. Color-coding is used to visually show the coordinator which trial they are working with (cyan background). The menu items on the left represent the viewing of the data as a whole. The data seen from these options are not specific to individual participants but to the whole trial.

The coordinator has the option of viewing and picking an existing participant from clicking on the name and choosing "Edit Patient", or just double-clicking on the name. For participants not yet in the computer, the coordinator chooses "Add Patient". The screens that follow are listed below.

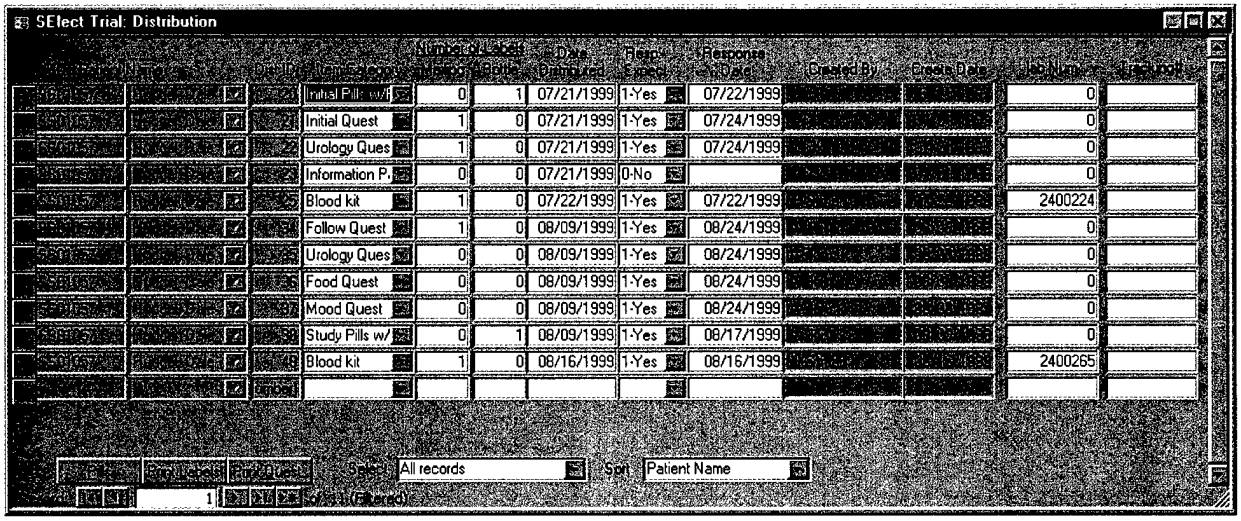


Below is the starting point after choosing a participant. The main screen shows the status of the participant and all the latest and important information. The top portion is the menu system to bring up each individual form or questionnaire.

This screen is the first place the coordinator goes to enter data for a new participant or starts from for updating for existing participants. The PatientID is automatically generated with new participants and it includes a check-digit within the value. Even though the entry of a PatientID is rarely performed, the check-digit will prevent an accidentally entered value. Other critical fields (i.e. Lab number) also include a check-digit to prevent miss-assignment of data. Important dates are entered or shown from this screen, along with the status of each participant. If the participant meets eligibility, the randomization is performed on this screen.

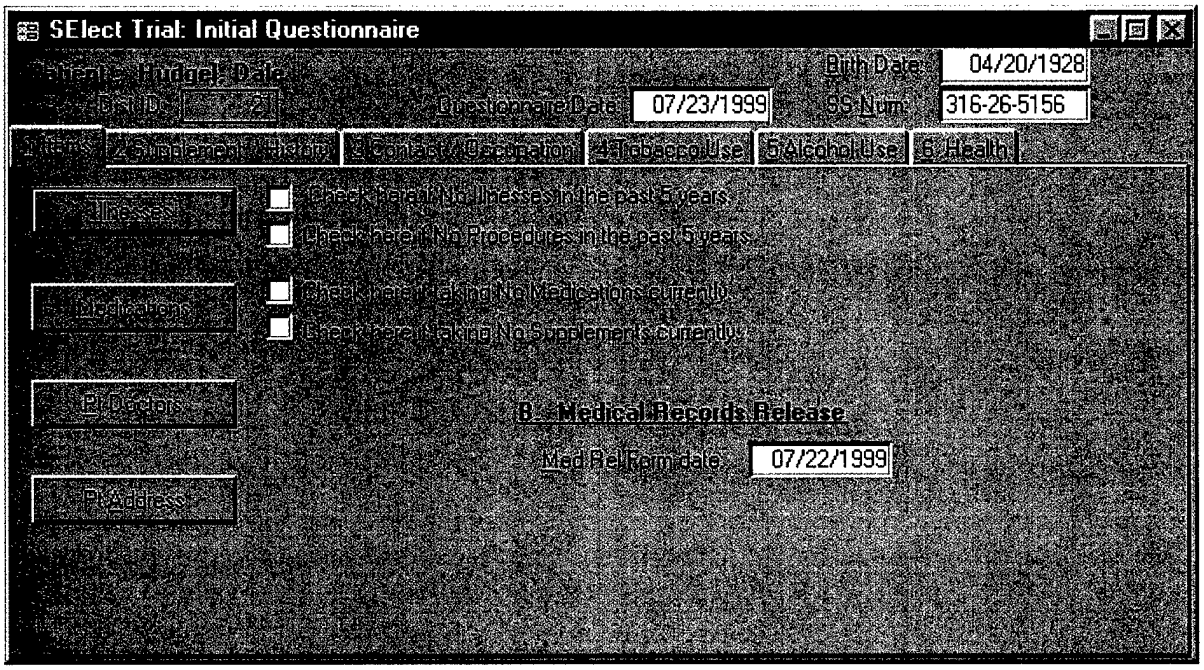


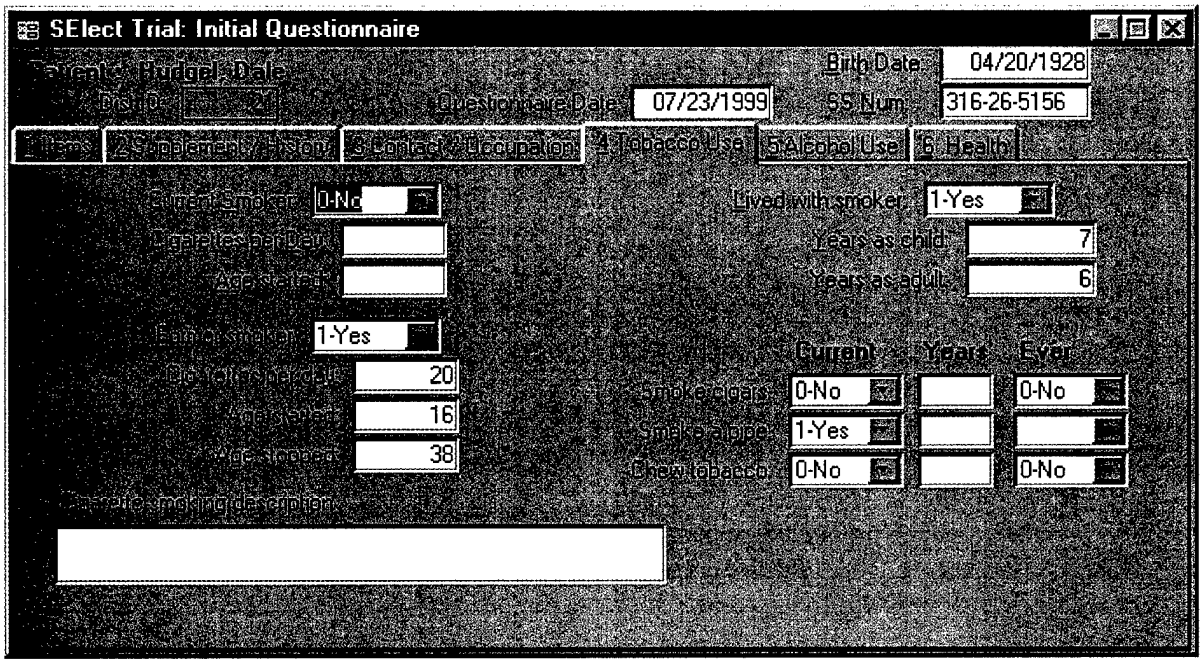
As discussed above, the Distribution table is the second most common table the coordinator uses. This table tracks everything that is sent out to the participant. If tracks what is sent out (and when) and what is expected back (and when). If we send something out, expect it back, and is not returned, this table and corresponding report will highlight what needs following up. As you can see from the screen shot, this participant has had several items sent to him on different dates: Pills, several different questionnaires, and blood kits.



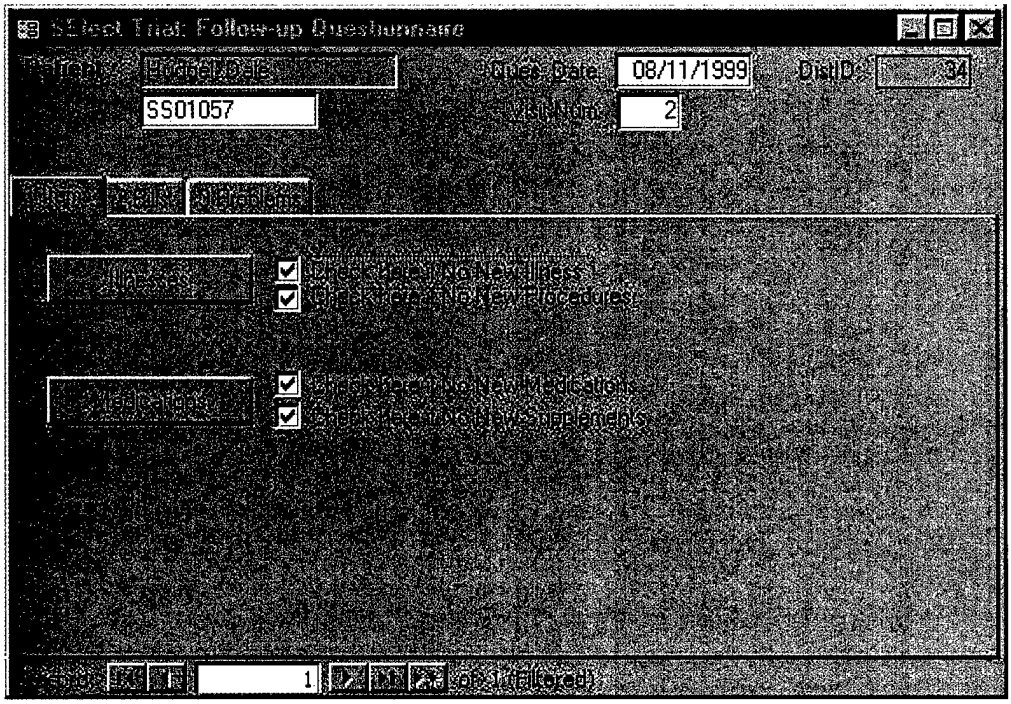
Here are some screen-shots of forms that represent the hardcopy questionnaires. The first questionnaire that the participant needs to complete is the Initial Questionnaire collecting baseline information.

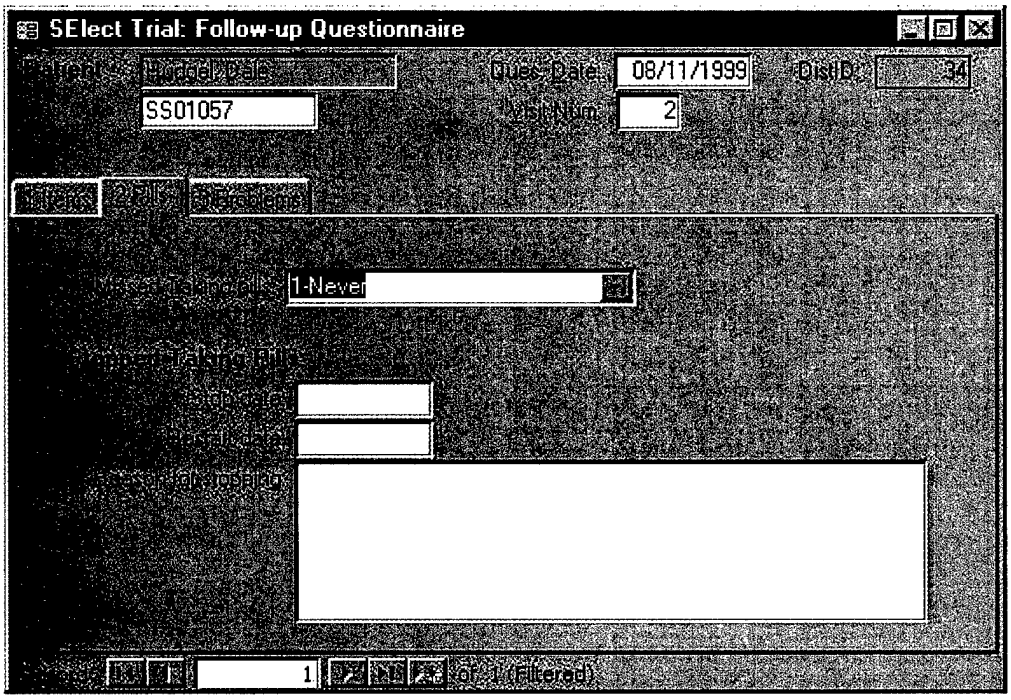
Most forms have access to the common input routine for Illness events and medication including east access to their doctors and address. This and the next screen-shot shows what is behind a tab that reflects each region or area on the hardcopy questionnaire.

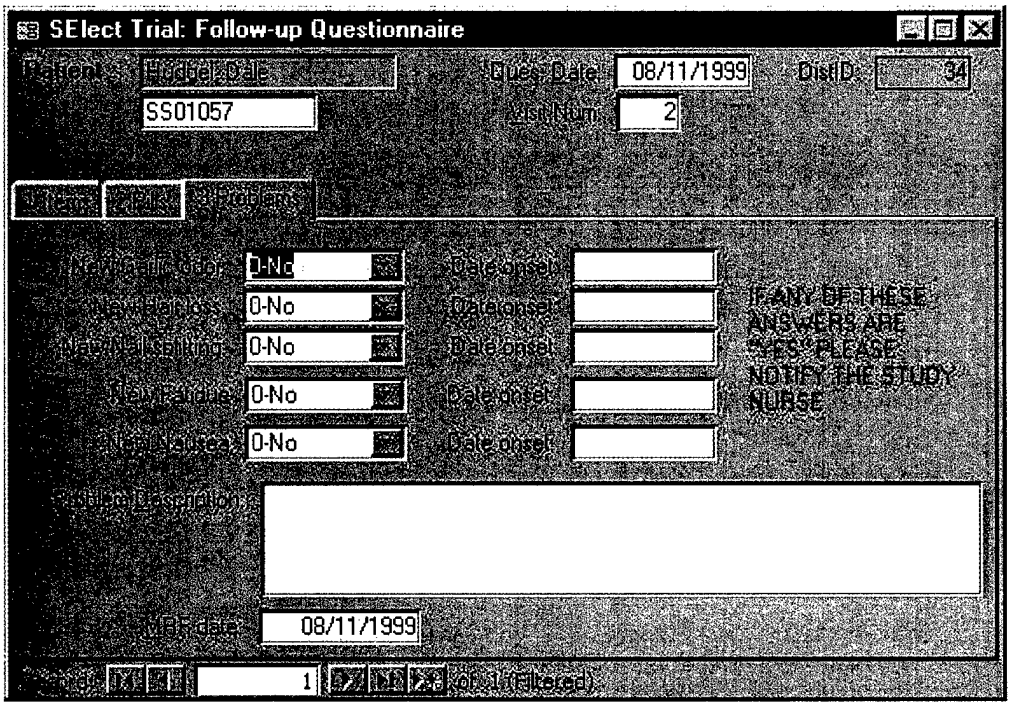




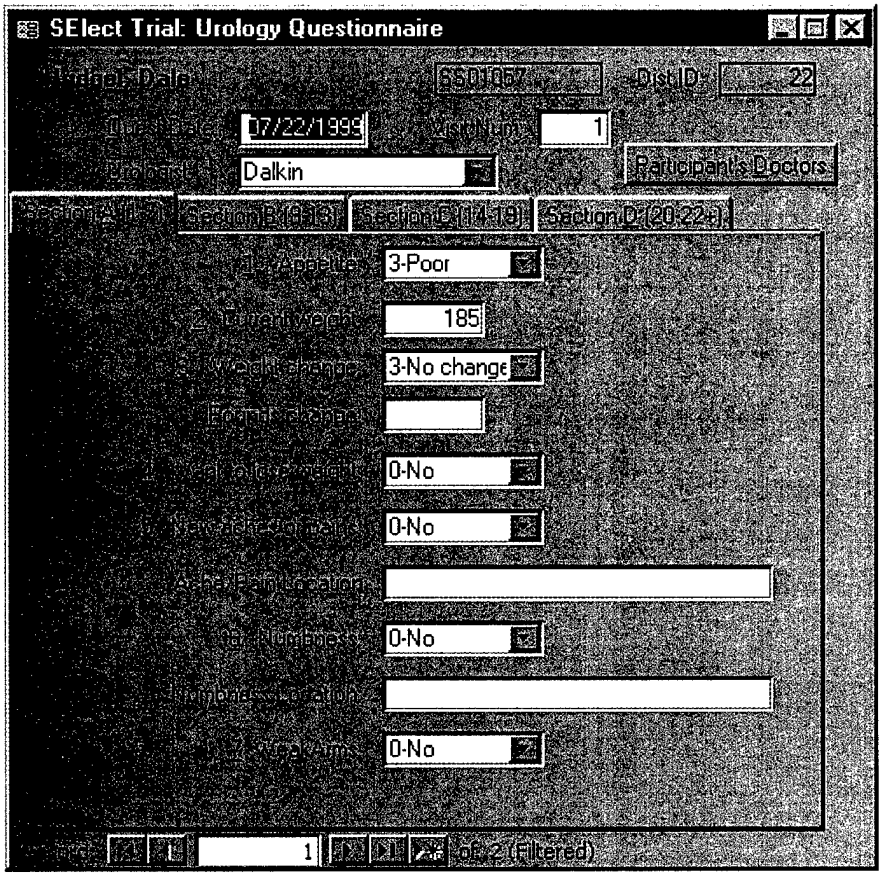
The following three screen-shots show each section of the follow-up questionnaire. Again, the first image allows for a common entry point for illness events and medication usage. The other images checks for compliance and any possible adverse effects.



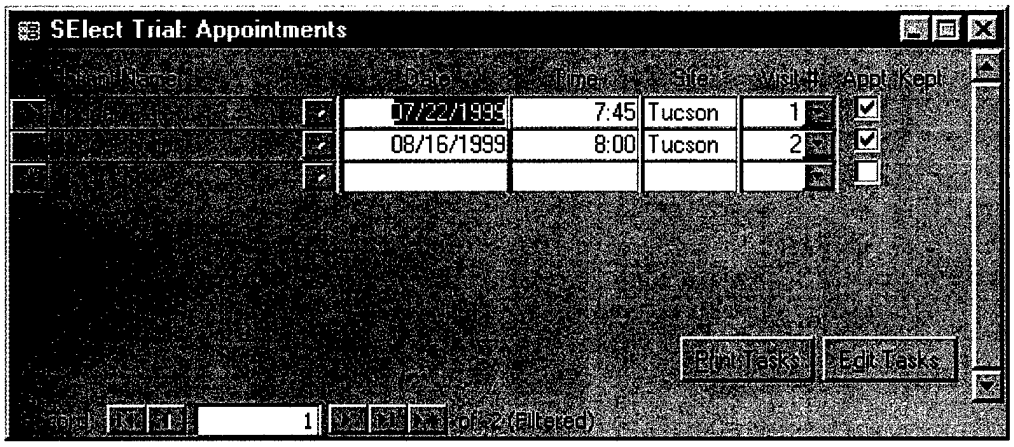


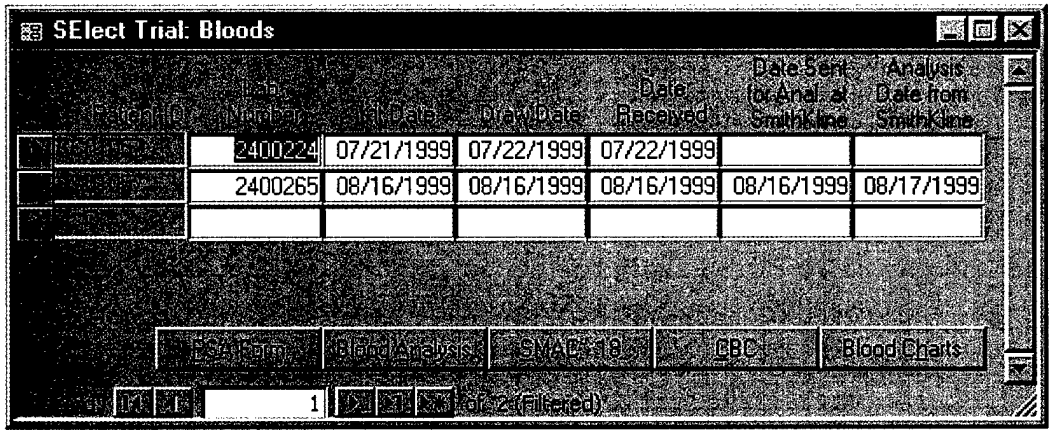


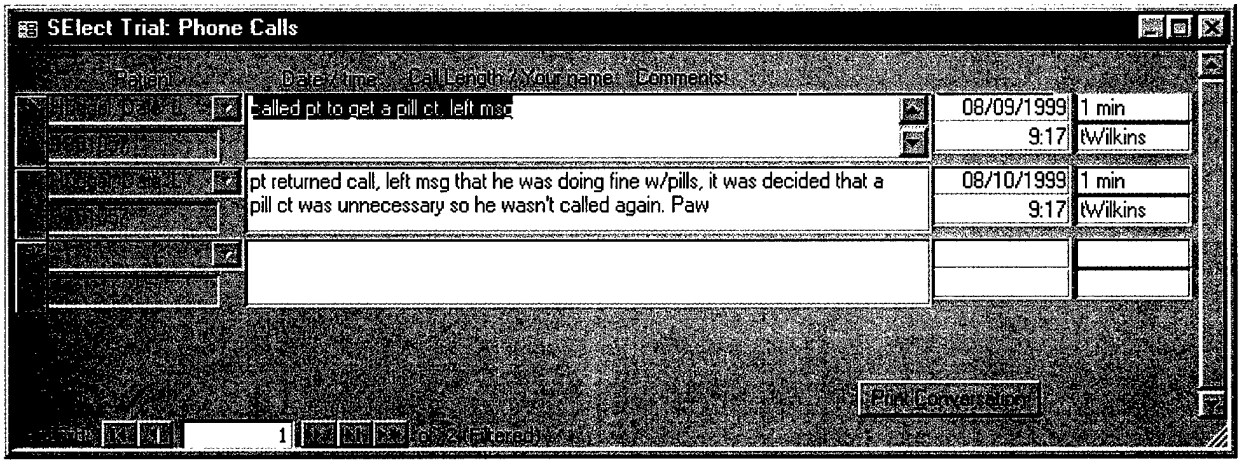
The Urology form has many questions relating to the prostate. Each tabbed section reflects a separate page on the hard-copy questionnaire.



The following are screen-shoots of other forms that are filled out through he course of trial and are self-explanatory.

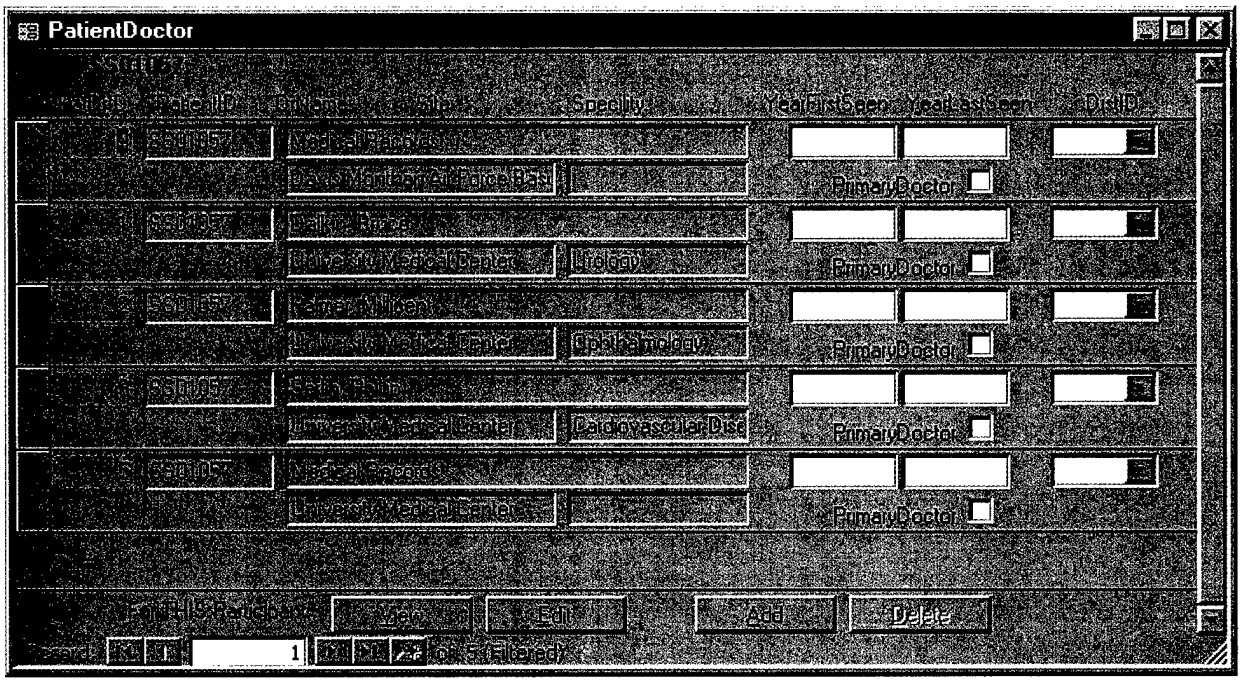






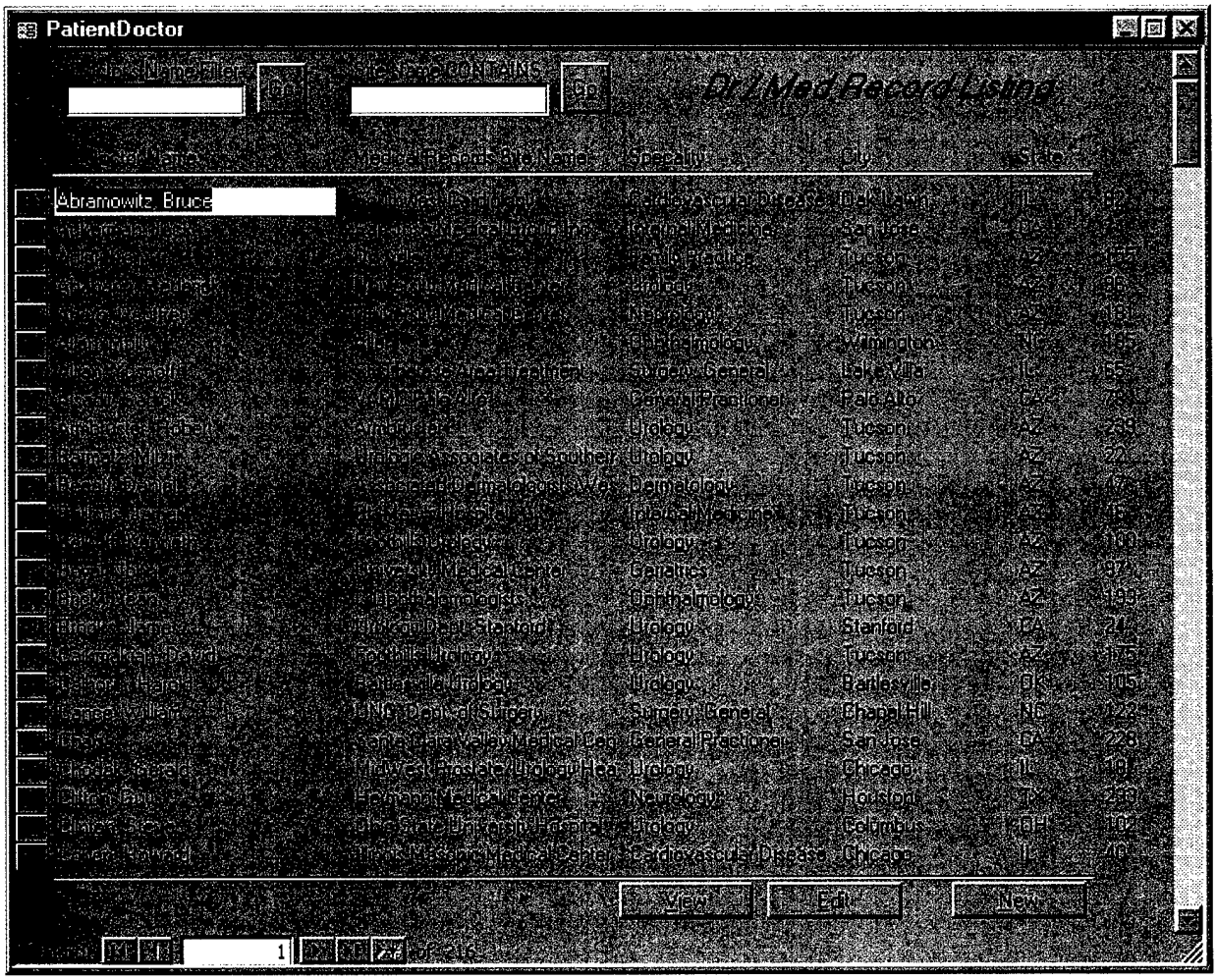
Due to the fact that all illness events are patient reported, we have a illness documentation system to confirm each report. For confirmation, we track all the doctors listed from each participant.

The screen below lists doctors for this one participant.

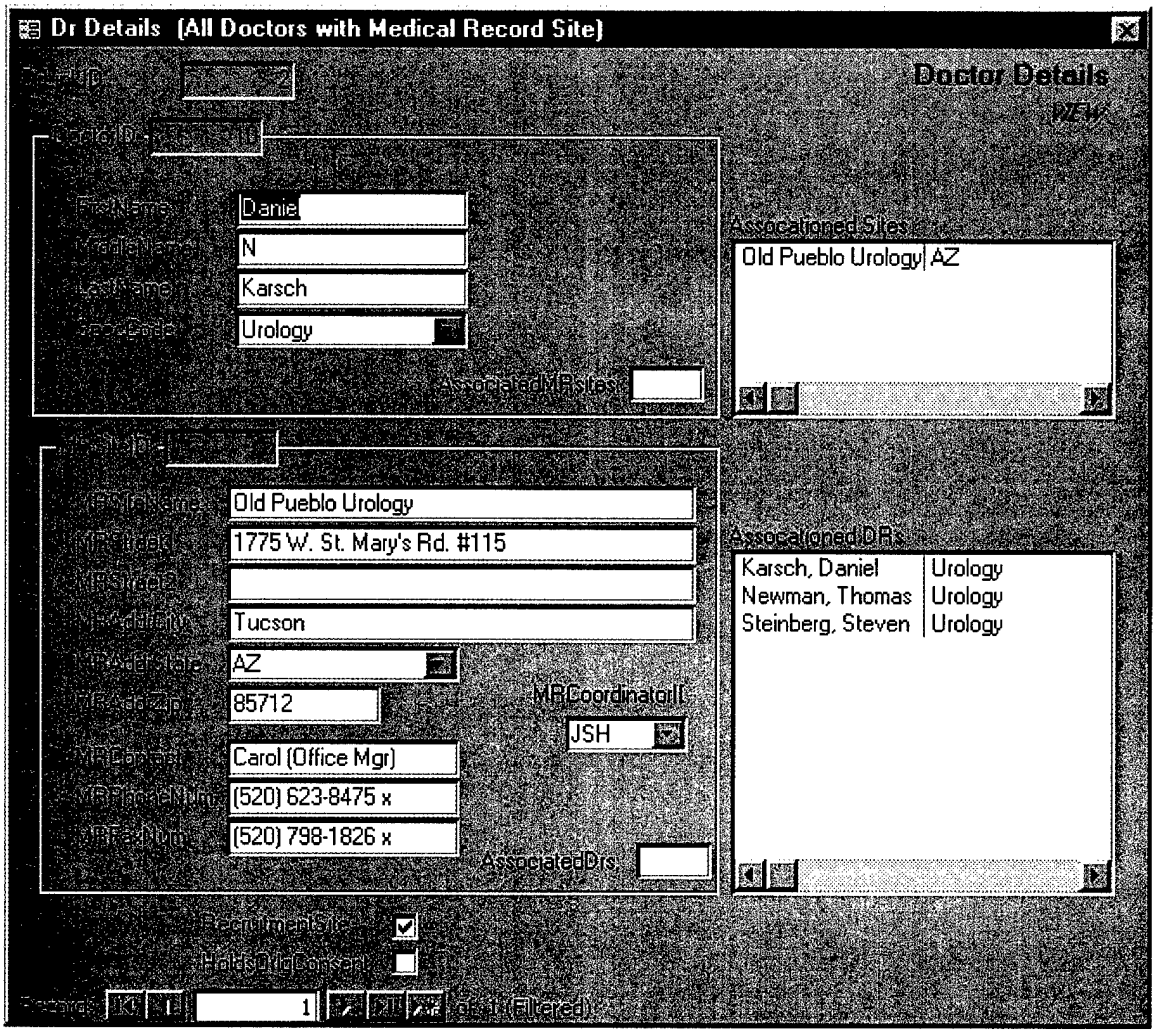


This is the screen showing all the current doctors that can be chosen from. A search criteria is used for either the doctor's name, or from the site name. Additional information is listed along side to help pinpoint the correct location.

The main concern for us, is the ability to obtain medical records for the participants. So we have recorded a doctor and the associated site where the medical records department address is located. The example below shows that this Medical Records Site has three collaborating doctors.



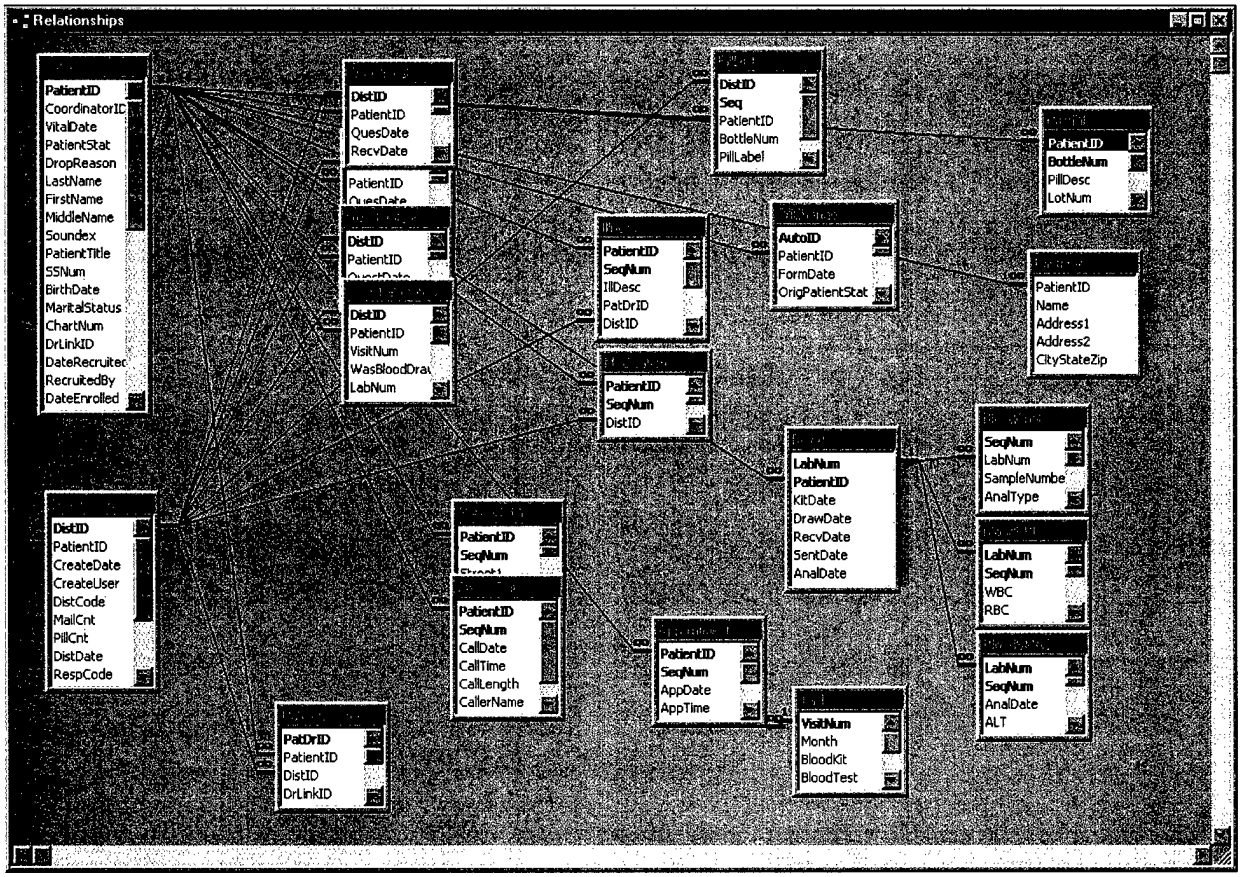
And this screen shows the ability to edit each doctor. The complexity is hidden that shows the many-to-many relationship between doctors and medical sites. A doctor can belong to many institutes and an institute has many doctors.



SElect Study
Computer Program Interface.

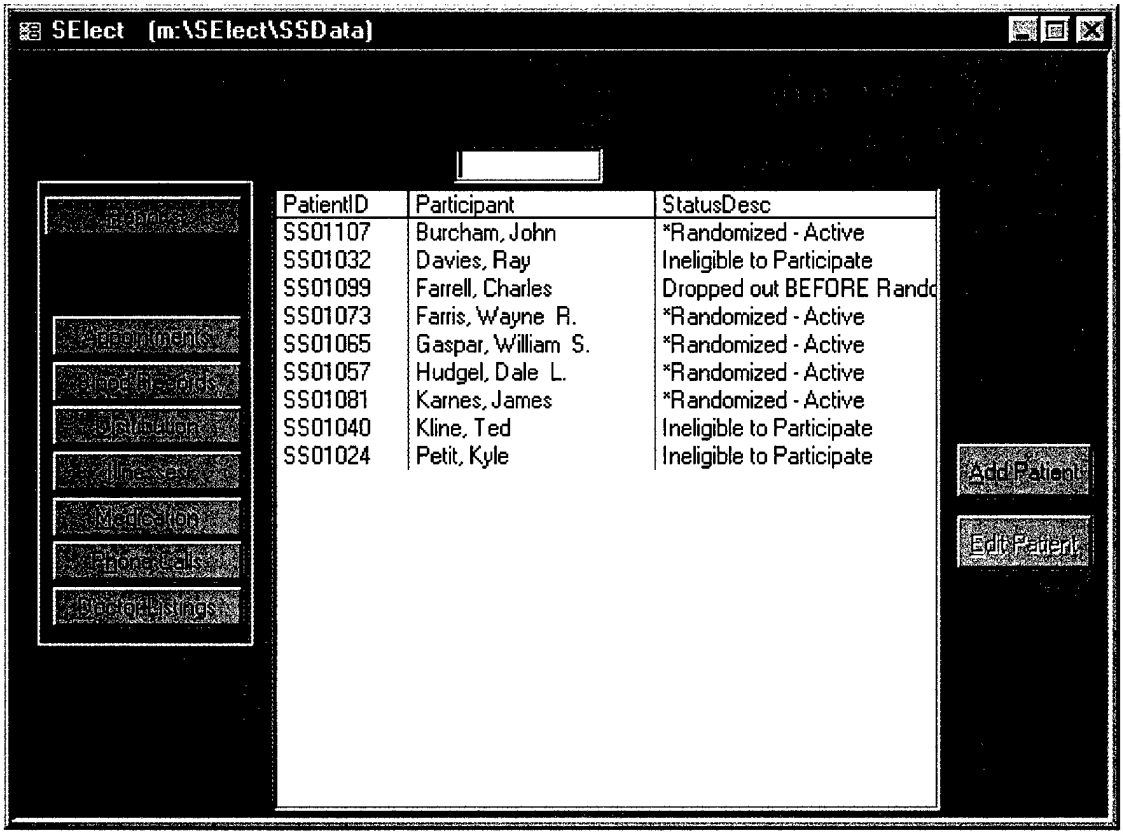
The following are screen images of what the computer program looks like. Not all screens are displayed and only represent a portion of what is used to run the SElect Study. There are many functions and capabilities this software has that is not represented here. For example, anything from the randomization process, to the assignment of participant IDs, the processing of bloods, to validating information already entered.

The image below represents most to the tables used in the trial (excludes standard lookup tables and other external tables used in all trials). The focus that needs to be shown is everything relies on two main tables – (1) the Patient table in the top left corner, and (2) the distribution table below that. This relational database structure is keyed to keeping all reference integrity based upon the unique PatientID field. All program coding automatically keeps the data intact. No manually entered PatientIDs is required. The Distribution table is used to track every item that goes out of the coordinating center to participants. More of this mentioned below.

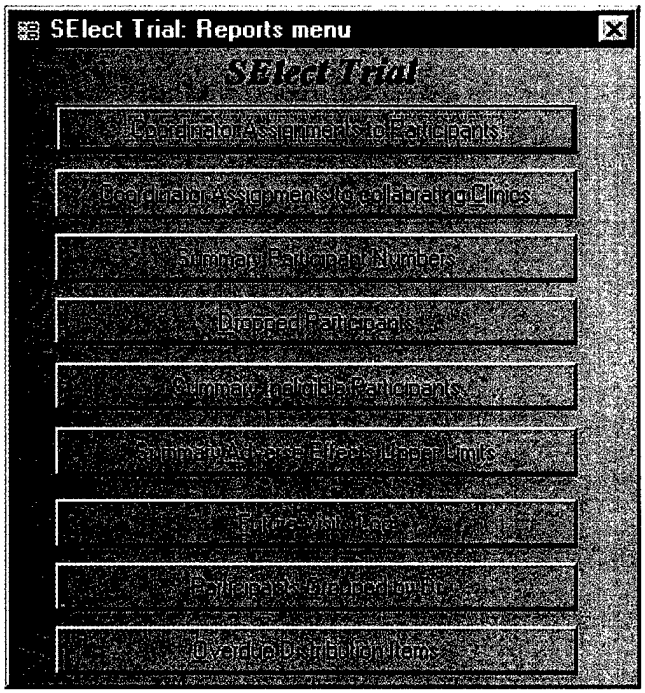


The first screen the coordinator sees is the main menu stating what program they are using. Color-coding is used to visually show the coordinator which trial they are working with (cyan background). The menu items on the left represent the viewing of the data as a whole. The data seen from these options are not specific to individual participants but to the whole trial.

The coordinator has the option of viewing and picking an existing participant from clicking on the name and choosing "Edit Patient", or just double-clicking on the name. For participants not yet in the computer, the coordinator chooses "Add Patient". The screens that follow are listed below.



The Reports button brings up the following screen to where the coordinator can display any number of reports to help run the trial. Other reports are created as needed.



Here is an example of a report showing a single page of which participants where assigned to the coordinator "PAW". This report allows the coordinator to quickly determine the status of each of their participants and take any actions necessary.

SElect Trial **Coordinator's Participants** *Confidential* *Page 3 of 3*

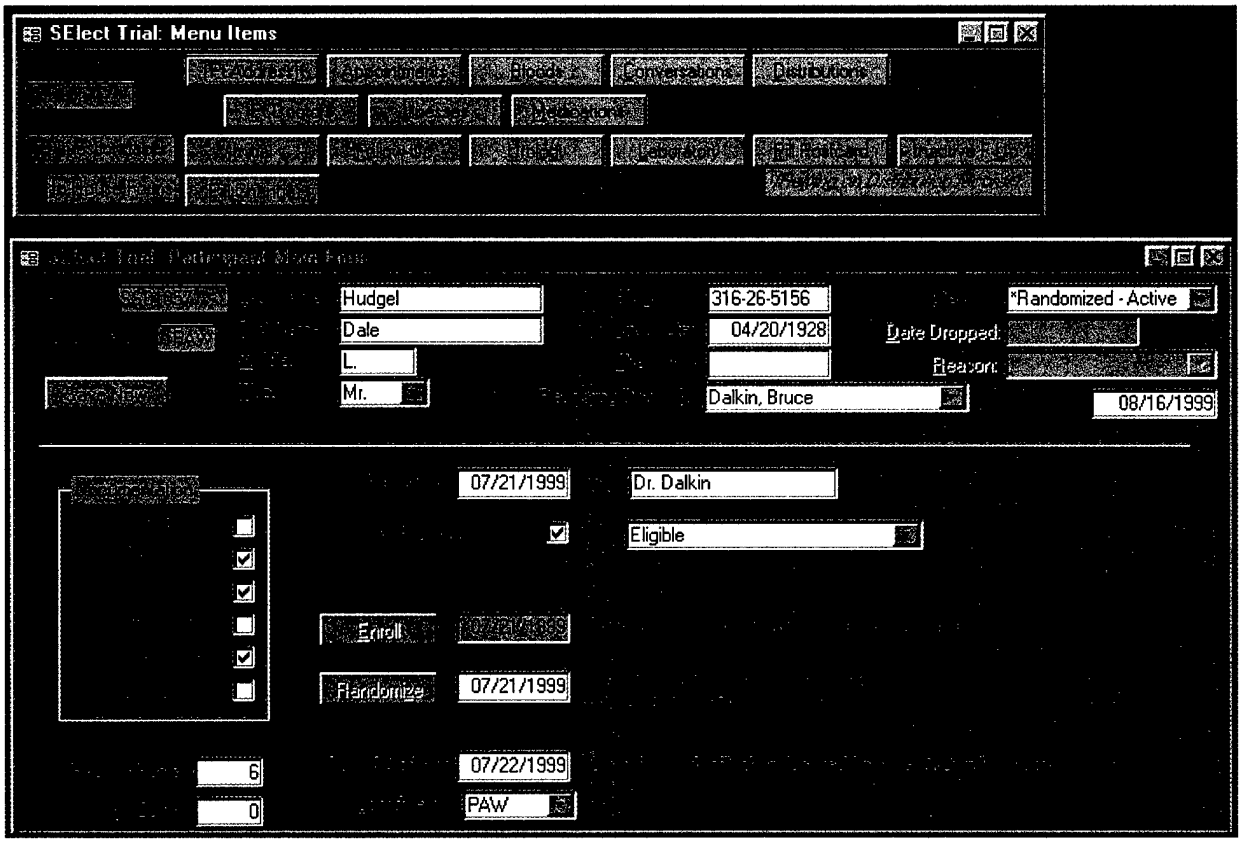
hursday, October 28, 1999 10:55:52 AM

ID	*Name*		*Recruited*	*Enrolled*	*Randomized*	*Took 1st Pill*	*Dropped*	
Coordinator	PAW							
SS01057	Hudgel	Dale	7/21/1999	7/21/1999	7/21/1999	7/22/1999		
SS01081	Karnes	James	8/18/1999	8/27/1999	9/6/1999	8/28/1999		
SS01040	Kline	Ted	6/29/1999	6/29/1999			7/1/1999	Didn't meet eligibility criteria
SS01024	Petit	Kyle	6/28/1999	6/29/1999			7/8/1999	Didn't meet eligibility criteria

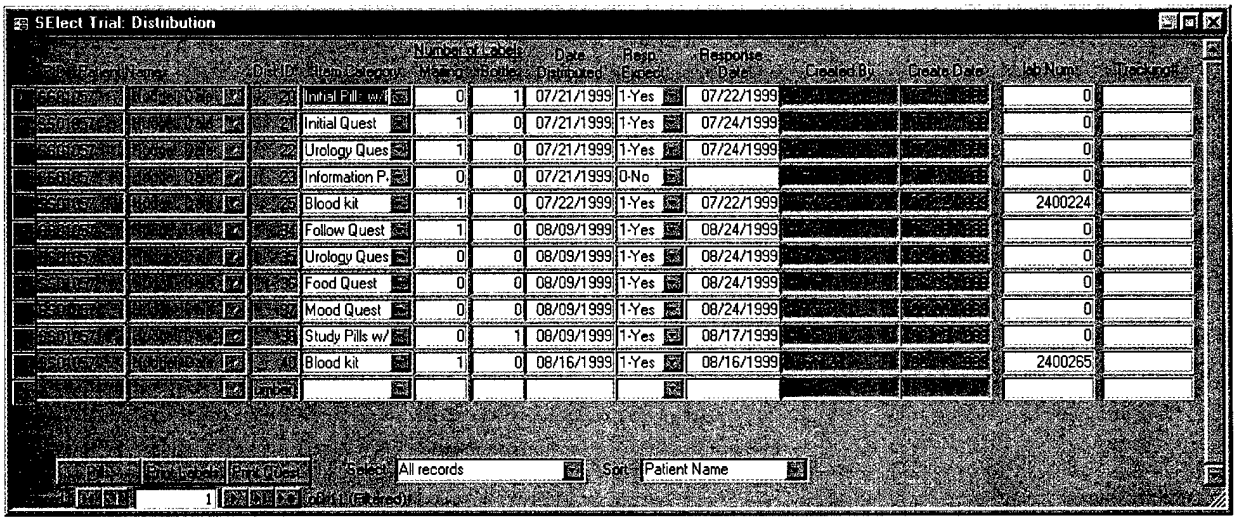
Total Number Recruited:	4	*Total Recruited then Dropped:*	0
Total Number Enrolled:	4	*Total Enrolled then Dropped:*	2
Total Number Randomized:	2	*Total Randomized then Dropped:*	0
Total Number took 1st Pills:	2	*Total Dropped Participants:*	2
		Total Recruited not yet Enrolled:	0
		Total Enrolled not yet Randomized:	0
		Total Pre-Randomized Active Participants:	0
		Total Randomized Active Participants:	2
		Total Active Participants:	2

Below is the starting point after choosing a participant. The main screen shows the status of the participant and all the latest and important information. The top portion is the menu system to bring up each individual form or questionnaire.

This screen is the first place the coordinator goes to enter data for a new participant or starts from for updating for existing participants. The PatientID is automatically generated with new participants and it includes a check-digit within the value. Even though the entry of a PatientID is rarely performed, the check-digit will prevent an accidentally entered value. Other critical fields (i.e. Lab number) also include a check-digit to prevent miss-assignment of data. Important dates are entered or shown from this screen, along with the status of each participant. If the participant meets eligibility, the randomization is performed on this screen.

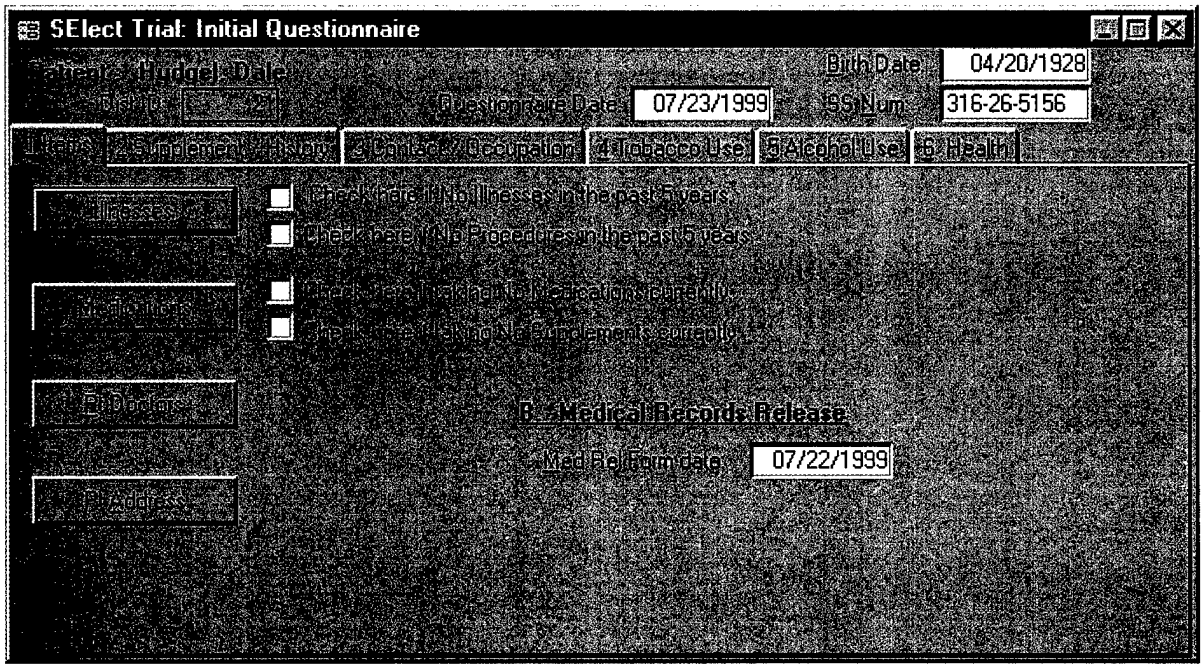


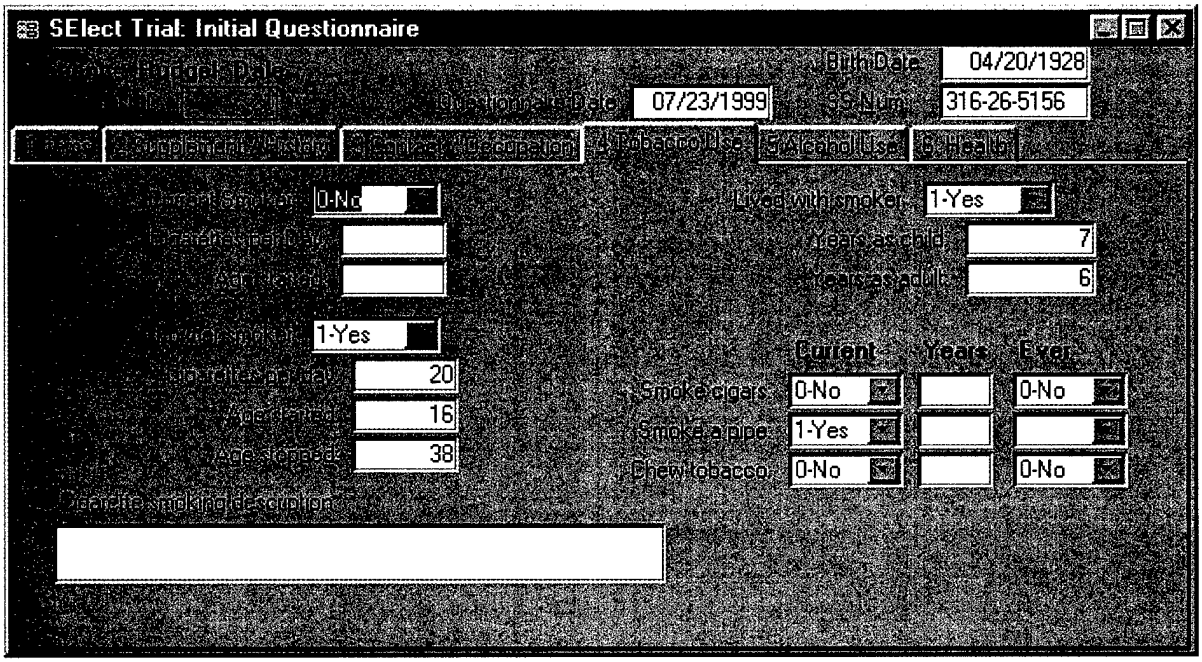
As discussed above, the Distribution table is the second most common table the coordinator uses. This table tracks everything that is sent out to the participant. If tracks what is sent out (and when) and what is expected back (and when). If we send something out, expect it back, and is not returned, this table and corresponding report will highlight what needs following up. As you can see from the screen shot, this participant has had several items sent to him on different dates: Pills, several different questionnaires, and blood kits.



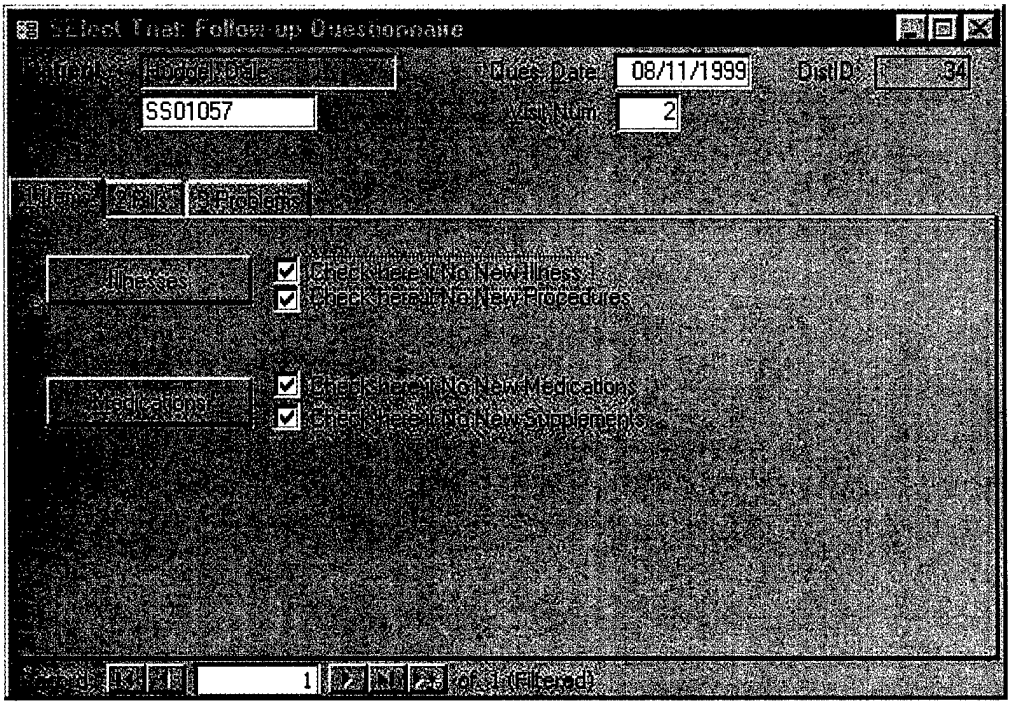
Here are some screen-shots of forms that represent the hardcopy questionnaires. The first questionnaire that the participant needs to complete is the Initial Questionnaire collecting baseline information.

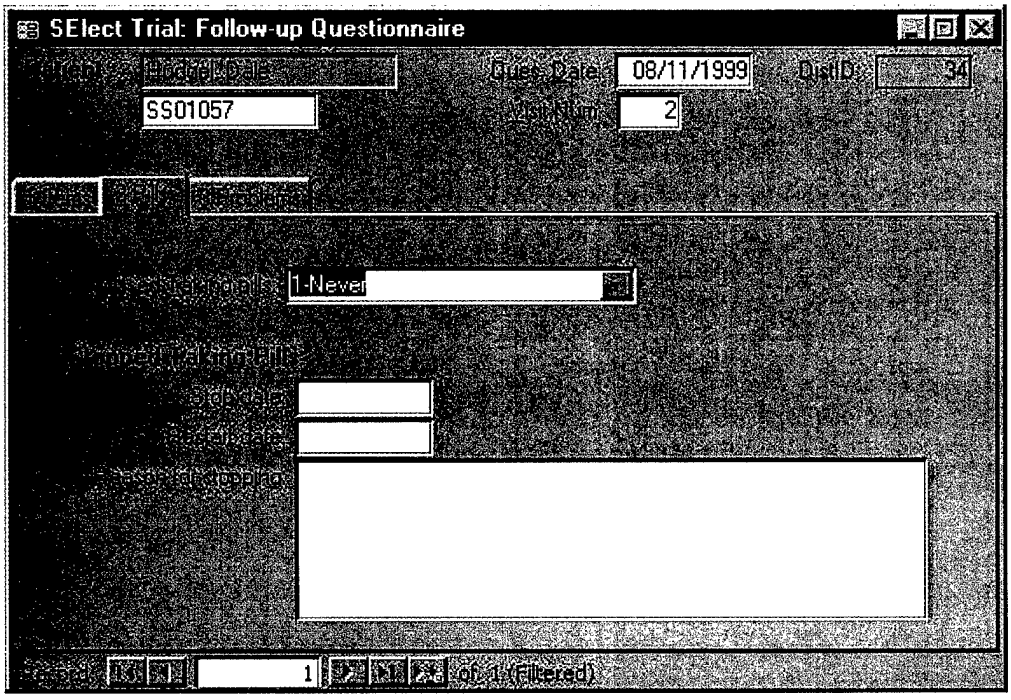
Most forms have access to the common input routine for Illness events and medication including east access to their doctors and address. This and the next screen-shot shows what is behind a tab that reflects each region or area on the hardcopy questionnaire.

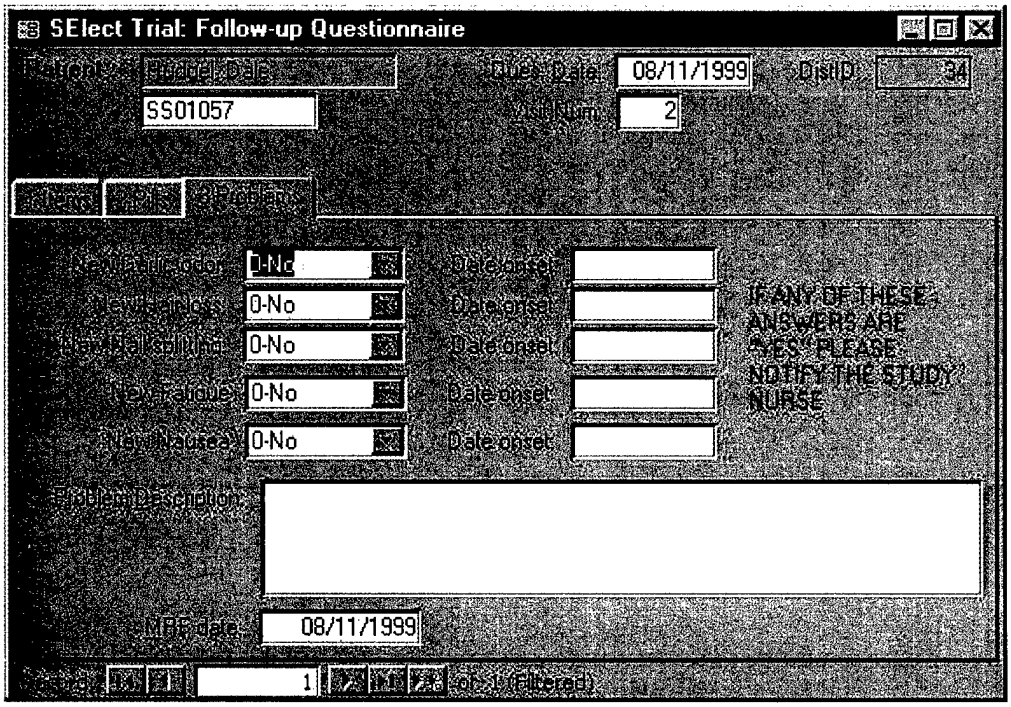




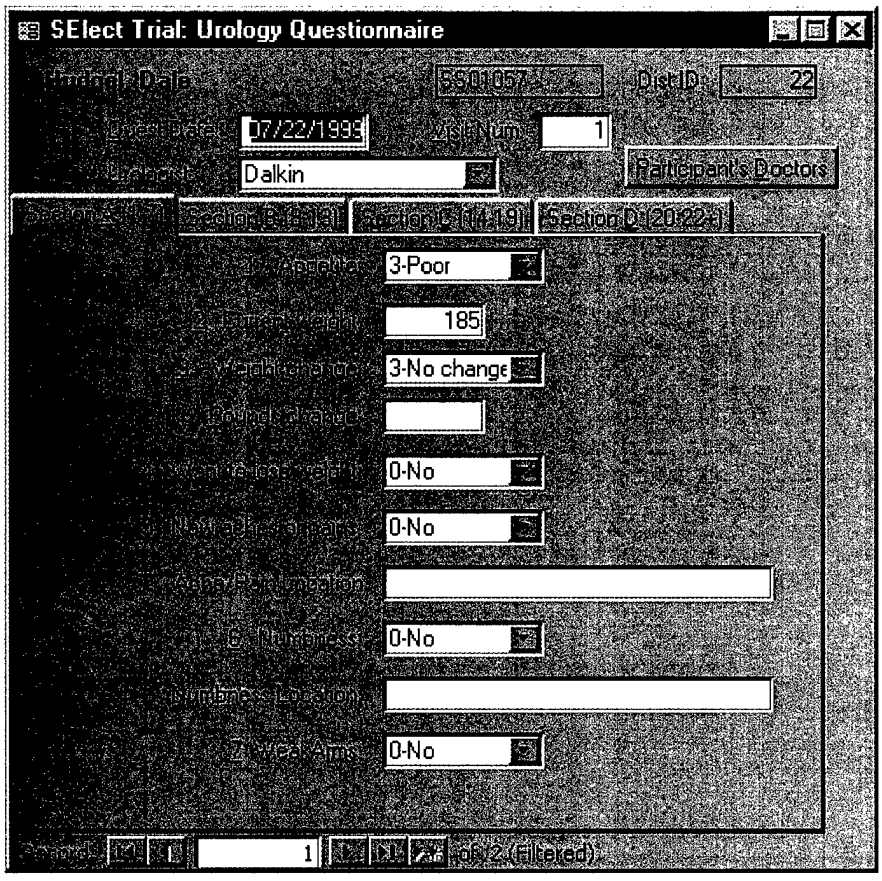
The following three screen-shots show each section of the follow-up questionnaire. Again, the first image allows for a common entry point for illness events and medication usage. The other images checks for compliance and any possible adverse effects.



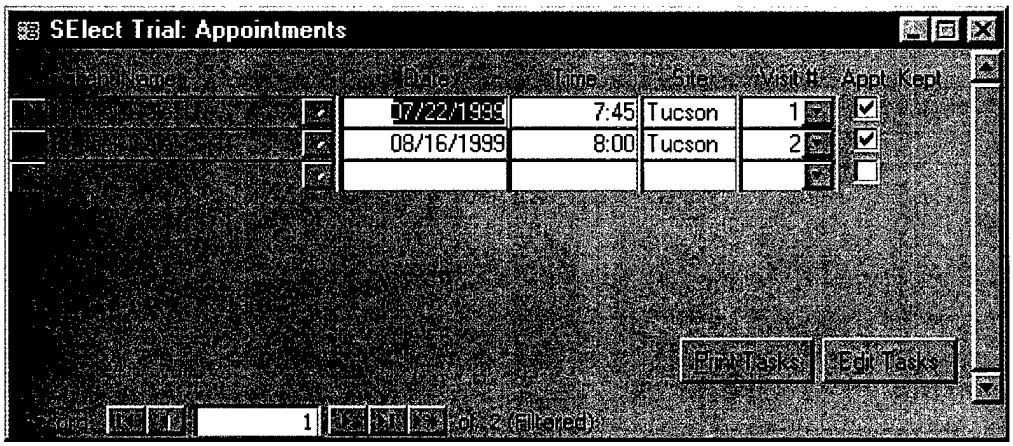


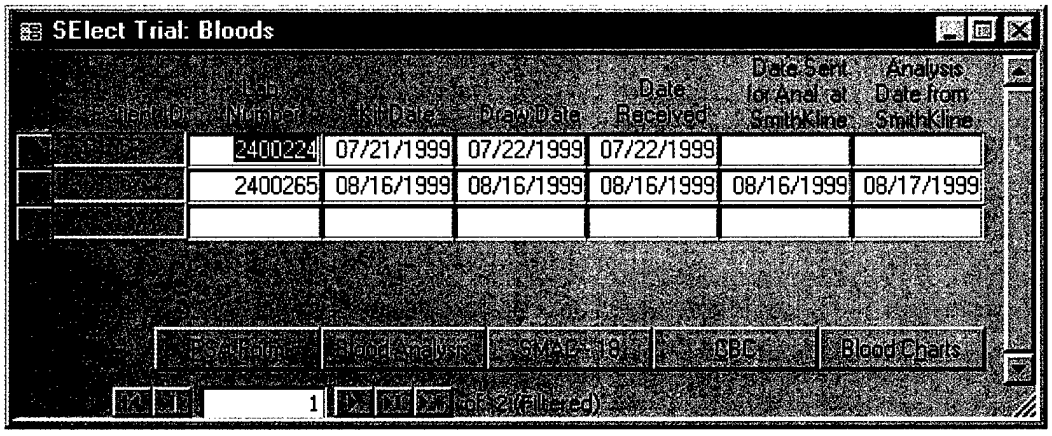


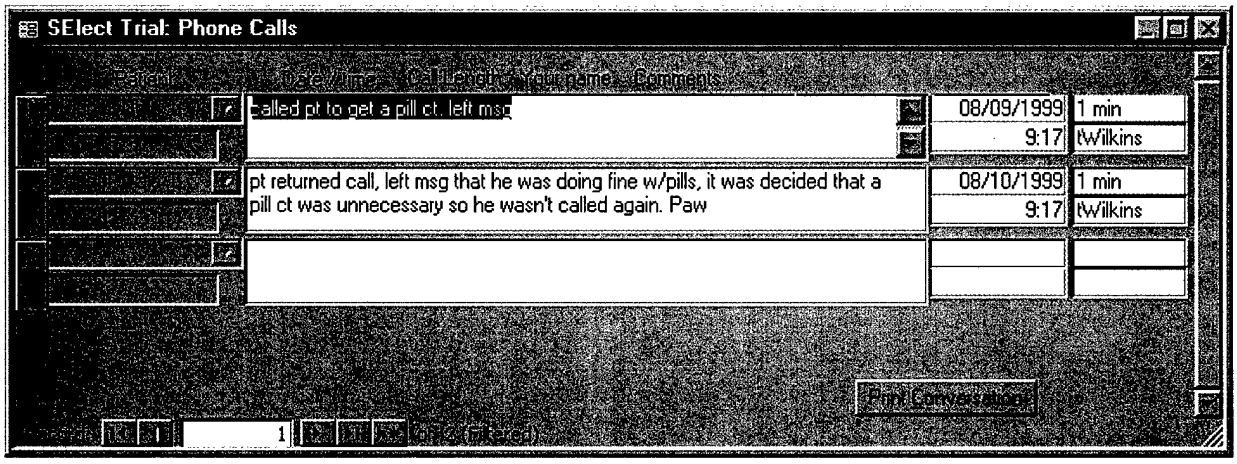
The Urology form has many questions relating to the prostate. Each tabbed section reflects a separate page on the hard-copy questionnaire.



The following are screen-shoots of other forms that are filled out through he course of trial and are self-explanatory.

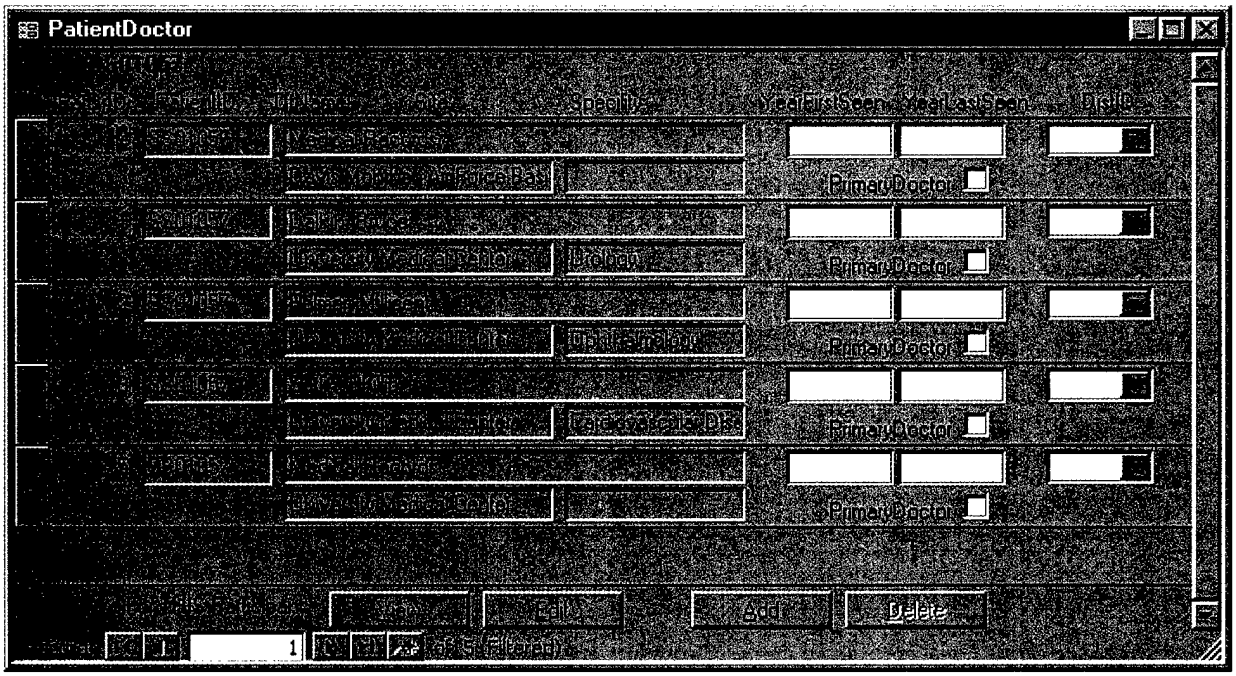






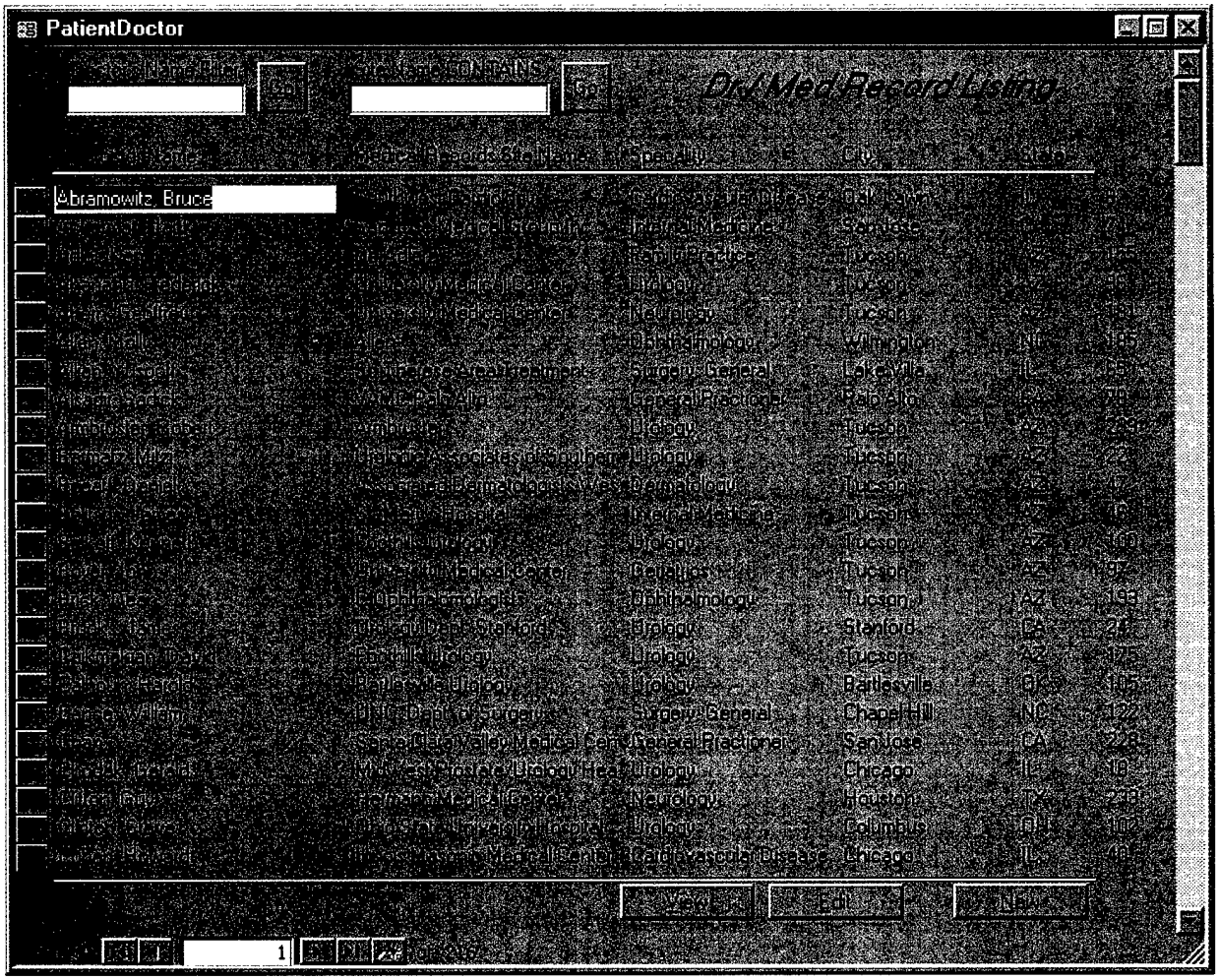
Due to the fact that all illness events are patient reported, we have a illness documentation system to confirm each report. For confirmation, we track all the doctors listed from each participant.

The screen below lists doctors for this one participant.

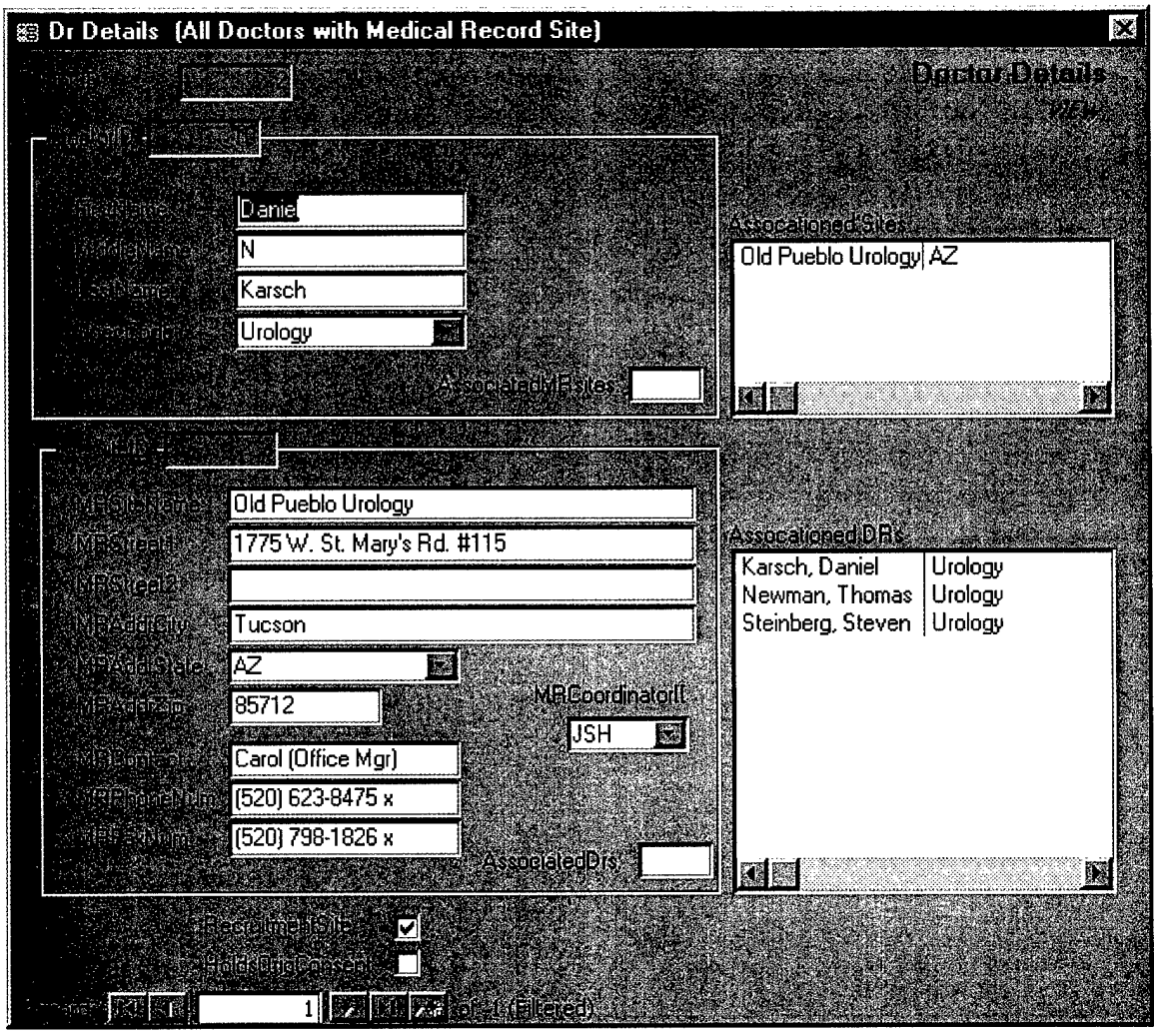


This is the screen showing all the current doctors that can be chosen from. A search criteria is used for either the doctor's name, or from the site name. Additional information is listed along side to help pinpoint the correct location.

The main concern for us, is the ability to obtain medical records for the participants. So we have recorded a doctor and the associated site where the medical records department address is located. The example below shows that this Medical Records Site has three collaborating doctors.



And this screen shows the ability to edit each doctor. The complexity is hidden that shows the many-to-many relationship between doctors and medical sites. A doctor can belong to many institutes and an institute has many doctors.



Appendix IV: Summary of IRB Approval Status

Select Trial
Urologist IRB status

Last	First Name	Clinic Location	IRB Approval Status
Barmatz,	Mitzi	Tucson, AZ	Approved
Dalkin,	Bruce	Tucson, AZ	Approved
Dickstein,	Steven	Tucson, AZ	Approved
Greenberg,	Jerry	Tucson, AZ	Approved
Herlong,	James	Columbia, SC	Approved
Hicks,	Thomas	Tucson, AZ	Approved
Hirsch,	Irwin	Philadelphia, PA	Approval pending
Janosko,	Edward	Greenville, NC	Approved
Kalota,	Susan	Tucson, AZ	Approved
Marks,	Sheldon	Tucson, AZ	Approved
Mohler,	James	Chapel Hill, NC	Approved
Terris,	artha K.	Palo Alto, CA	Approval pending

P:\SElect Study\Progress Reports\Annual Report\Urologist IRB status.doc

Appendix V

Immunohistochemical studies of surrogate markers

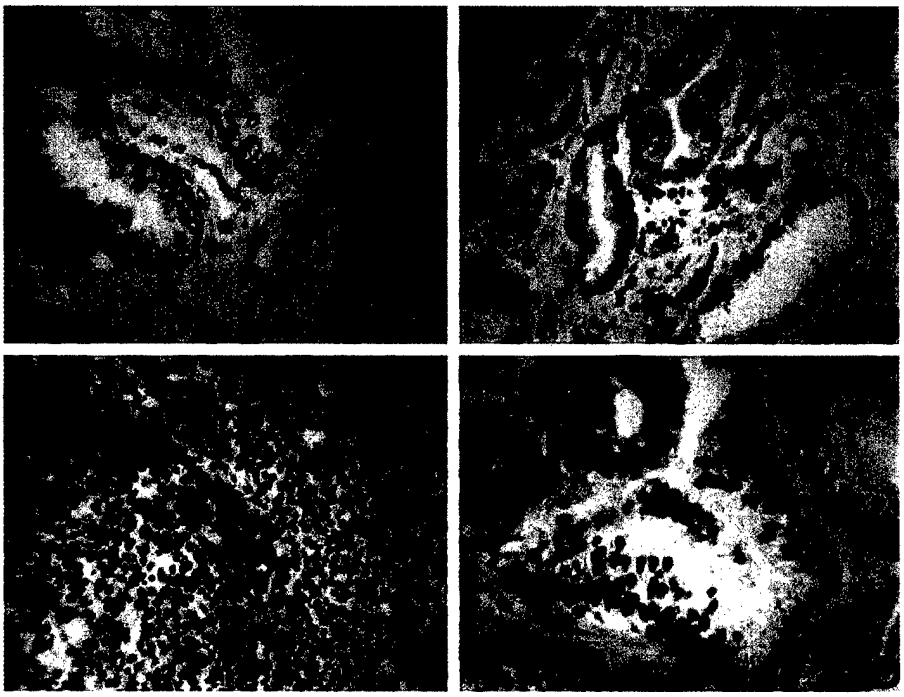


Figure 1

A) Basel cell cytokeratins specific stain of non-Ca prostate glands
B) Basel cell specific stain of prostate glands, not absence of basel cells around cancerous glands
C) Pos control lymph node stained for Ki-67, note highly proliferative germinal center
D) Ki-67 on prostate cancer showing a low rate of proliferation

CURRICULUM VITAE
LARRY C. CLARK

Associate Professor of Epidemiology
Arizona Cancer Center
University of Arizona
2504 E. Elm Street
Tucson, AZ 85716
TEL: (520) 321-7798 1-800-243-6519
FAX: (520) 321-7774
E-mail: lcClark@u.arizona.edu

PII Redacted

EDUCATION

B.S.	Alma College (Alma, MI), Biology	1970
M.P.H.	University of Michigan (Ann Arbor), Epidemiology	1974
Ph.D.	University of North Carolina (Chapel Hill), Epidemiology	1982

Dissertation: A Case Control Study of Skin Neoplasms and the Anticarcinogenic Effects of Selenium.
Dissertation Committee Chair: Carl M. Shy, M.D., Dr.P.H.

MAJOR FIELDS OF INTEREST

- Cancer Prevention
- Diet and Cancer Epidemiology
- Environmental Epidemiology
- International Health

PROFESSIONAL SOCIETIES

- American Association for Cancer Research
- American College of Epidemiology
- American Institute of Nutrition
- American Society for Preventive Oncology
- International Environmental Epidemiology Association
- International Association for Vitamin and Nutritional Oncology
- Society for Epidemiologic Research

ACADEMIC AND PROFESSIONAL APPOINTMENTS

UNIVERSITY OF ARIZONA

1999-present	Adjunct, Associate Professor, College of Agriculture, Department of Nutritional Sciences
1994-1995	Director, Epidemiology Program, Arizona Cancer Center, College of Medicine
1992-present	Associate Professor of Epidemiology, College of Medicine, Arizona Prevention Center
1987-1992	Assistant Professor of Epidemiology, College of Medicine, Department of Family and Community Medicine

CORNELL UNIVERSITY

1986-1987	Assistant Professor of Epidemiology, College of Agriculture and Life Sciences, Biometrics Unit
1982-1986	Assistant Professor of Epidemiology, School of Veterinary Medicine, Department of Preventive Medicine
1982-1987	Joint Appointment with the Division of Nutritional Sciences

UNIVERSITY OF NORTH CAROLINA

1978-1980	Epidemiologist - IPA Assignment, National Institute for Environmental Health Sciences, Biometry Branch, Research Triangle Park
1975-1980	Research Assistant, Department of Epidemiology
1975-1978	Project Director, Pesticide Use and Cancer Mortality Study, Institute for Environmental Studies

UNIVERSITY OF MICHIGAN

1974-1975	Research Assistant, Department of Epidemiology

WORLD HEALTH ORGANIZATION-ACTION

1971-1974	Surveillance Officer, Smallpox Eradication Program in Ethiopia

HONORS

AWARDS

- Cover Feature, Cancer Research, in recognition of the importance of joint Research in Selenium and Cancer Prevention with B.S. Reddy, K. El-Bayoumy, and E.S. Fiala, October, 1999
- Pioneer Science Award, Cancer Treatment Research Foundation, Research on Selenium and Human Cancer, 1997
- Dedication in *Prostate and Cancer A Family Guide to Diagnosis, Treatment, and Survival*, Sheldon Marks, 1999

SCIENTIFIC REVIEW COMMITTTEES

- American Cancer Society
- National Cancer Institute
- Center for Disease Control

PROGRAM REVIEW COMMITTEES

1995 Chair, Program Project Site Visit Team, American Health Foundation, Valhalla, NY
1990 Scientific Board of Councilors Extramural Review of the Biometry Branch, Division of Cancer, Prevention and Control, National Cancer Institute
1988 International Vitamin A Program, Agency for International Development

AD HOC REVIEWER

- American Cancer Society
- National Research Council
- Agency for International Development
- Center for Disease Control

PUBLICATIONS:

SCHOLARLY MONOGRAPHS:

1. **Clark, L.C.,** Giuliano, A., Walsh, B., Guernsey de Zapien, J., Reid, M.E., Meister, J., Mason, T.J., "The Community Health Survey for Santa Cruz County," October, 1994
2. **Clark, L.C**. "A Case Control Study of Skin Neoplasms and the Anticarcinogenic Effects of Selenium." Dissertation at the University of North Carolina at Chapel Hill, Chapel Hill, North Carolina. Diss. Abstr. (B) 42 (12 ptl.) 1982: 4753-B.

BOOK CHAPTERS (ORIGINAL RESEARCH):

1. **Clark, L.C.,** and Combs, Jr., G.F. "Selenium and Cancer" Pp. 215-222 in Nutritional Oncology, Academic Press, San Diego, CA, 1999.
2. Slate, E.H., **Clark, L.C.**, "Using PSA To Detect Prostate Cancer Onset: An Application Of Bayesian Retrospective And Prospective Changepoint Identification." Case Studies in Bayesian Statistics IV, eds. C. Gatsonis, B. Carlin, A. Carriquiry, A. Gelman, R. Kass, I. Verdinelli and M. West, Springer-Verlag, 511- 534, 1998.
3. Combs, G.F., and **Clark, L.C.** "Selenium and Cancer Prevention" in Garewal (ed) Antioxidant Nutrients and Disease Prevention, CRC Press, Boca Raton, NY, April 1997.
4. Waller, L.A., Turnbull, B.W., **Clark, L.C.**, Nasca, P. "Examining Spatial Patterns of Disease Incidence Data to Detect Clusters in a Rare Disease: A Case Study" Case Studies in Biometry, 1992.
5. Lippman, S.M., **Clark, L.C.**, Parkinson, D.W., Weber, R.S., Hong, W.K. "Pharmacologic Prevention and Therapy of Skin Cancer" Pp. 177-197 In: Chemo & Immuno Prevention of Cancer, Pastorino, U. and Hong, W.K. (Eds.), Thelme Medical Publishers, Inc., New York, 1991.

6. Graham, G.F., **Clark, L.C.** "Statistical Analysis in Cryosurgery of Skin Cancer." Pp. 101-107, Parish, L.C., Crissey, J.T. (eds.). Advances in Cryosurgery, New York, Elsevier, 1990.

7. **Clark, L.C.**, Graham, G.F., Turnbull, B.W., Bray, J., Hulka, B. and Shy, C.M. "Nonmelanoma Skin Cancer and Plasma Selenium: A Prospective Cohort Study." Pp.1122-1135. Combs, Jr., G.F., Spallholz, J.E., Levander, O.A. and Oldfield, J.E. (eds.). In The Third International Symposium on Selenium in Biology and Medicine Westport, CN:AVI Pub. Co., 1986.

8. Graham, G.F., **Clark, L.C.** "Statistical Update of Cryosurgery for Cancers of the Skin." Pp. 298-307, Zacarian, S.A. (ed.). Cryosurgery for Skin Cancer and other Cutaneous Disorders. St. Louis, Missouri: C.V. Mosby, 1985.

9. **Clark, L.C.**, Shy, C.M., Portier, K.M., Most, B.M., Florin, J.W. "Cancer Mortality and Agricultural Activity: An Association with Cotton Production and Large Farms." Pp.3-16 Leaverton, P.E. (ed.). In Environmental Epidemiology. New York, Praeger, 1982.

JOURNAL ARTICLES

1. Lin, H., McCulloch, C.E., Turnbull, B.W., Slate, E.H., **Clark, L.C.**, "A Latent Class Mixed Model For Analyzing Biomarker Trajectories with Irregularly Scheduled Observations," Statistics in Medicine (in press).

2. Nelson, M.A., Porterfield, B.W., Jacobs, E.T., **Clark, L.C.** "Selenium and Prostate Cancer Prevention." Seminars in Urologic Oncology 17 (2):91-96 May, 1999.

3. Jiang, W., Turnbull, B.W., **Clark L.C.** "Semiparametric Regression Models for Repeated Events with Random Effects and Measurement Error." Journal of the American Statistical Association 94 (445): 111-124 March, 1999.

4. **Clark, L.C.,** Dalkin, B., Krongrad, A., Combs, Jr., G.F., Turnbull, B.W., Slate, E.H., Witherington, R., Herlong, J.H., Janosko, E., Carpenter, D., Borasso, C., Falk, S., Rounder, J. "Decreased Incidence of Prostate Cancer with Selenium Supplementation: Results of a Double-Blind Cancer Prevention Trial." British Journal of Urology 81:730-734 May, 1998.

5. Redman, C., Scott, J.A., Baines, A.T., Basye, J.L., **Clark, L.C.**, Calley, C., Roe, D., Payne, C.M., Nelson, M.A.. "Inhibitory Effect Of Selenomethionine On The Growth Of Three Selected Human Tumor Cell Line." Cancer Letters 125 (1998):103-110.

6. Kramer, T.R., Noecker, R.J., Miller, J.M., Hutter, J.J., **Clark, L.C.** "The Histiocytoses Of Childhood: Orbital Involvement In Langerhans' Cell Histiocytoses." Opthamology, 124 (6): 814-24, 1997.

7. Luo, X., Turnbull, B.W., **Clark, L.C.**, "Likelihood Ratio Tests for a Change Point with Survival Data." Biometrika, 84:3:555-565, 1997.

8. Krongrad, A., **Clark, L.C.**, Lai, H., Soloway, M.S. and Lai, S. "Redistribution of Age-specific Prostate Cancer Stage at Diagnosis" Disease Management and Clinical Outcomes, 1:2:41-46 March/April 1997.

9. Redman, C., Xu, M.J., Peng, Y., Wymer, J.A., Payne, C., **Clark, L.C.**, Nelson, M.A., "Involvement of Polyamines in Selenomethionine Induced Apoptosis and Mitotic Alteration in Human Tumor Cells". Carcinogenesis, 18:6:1195-1202, 1997.

10. Alberts, D.S., Einspahr, J., Ritenbaugh, C., Aicken, M., Rees-McGee, S. Ritchie, J., Emerson, S., Mason-Liddil, N. Bettinger, L. Patel, J., Bellapravalu, S., Ramnujam, P.S., Phelps, J., and **Clark, L.C.** "The Effect of Wheat Bran Fiber and Calcium Supplementation on Rectal Mucosal Proliferation in Patients with Resected Adenomatous Colorectal Polyps." Cancer, Epidemiology, Biomarkers and Preventions. 6:161-169, March 1997.

11. Turnbull, B.W., Jiang, W. and **Clark, L.C.** "Regression Models for Recurrent Event Data: Parametric Random Effects Models with Measurement Error." Statistics in Medicine. 16:853-864, 1997.

12. **Clark, L.C.**, Combs, Jr., G.F., Turnbull, B.W., Slate, E.H., Alberts, D., Abele, D., Allison, J.R., Chalker, D.K., Chow, J., Dalen, J., Davis, L., Deal, R., Glover, R., Graham, G., Gross, E., Herlong, J., Kight, F., Krongrad, A., Lesher, J.L., Park, H.K., Rice, J.S., Rogers, A., Sanders, B., Smith, C.L., Smith, E.J., Taylor, J.R. "Effects of Selenium Supplementation for Cancer Prevention in Patients With Carcinoma of the Skin: A Randomized Controlled Trial." Journal of the American Medical Association. 276:24:1957-1963, 1996.

13. Ranjini, N., Turnbull, B.W., Slate, E.H., **Clark, L.C.** "A Computer Program for Sample Size and Power Calculations in the Design of Multi-arm and Factorial Clinical Trials with Survival Time Endpoints." Computer Methods and Programs in Biomedicine. 49;137-147, 1996.

14. Alberts, D.S., Ritenbaugh, C., Story J.A., Aicken, M., Rees-McGee, S., Buller, M.K, Atwood J., Phelps, J., Ramnujam, P.S., Bellapravalu, S., Patel, J., Bextinger, L., and **Clark, L.C.** "Randomized, Double-Blinded, Placebo-Controlled Study of the Effect of Wheat Bran Fiber and Calcium Supplementation on Fecal Bile Acids in Patients with Resected Adenomatous Colorectal Polyps". Journal of the National Cancer Institute. 88:81-92, 1996.

15. Manzone, H. Billings, P.C., Cumming, N., Feldman, R., **Clark, L.C.**, Odell, C.S. Horan A., Atiba, J.O. Meyskens, F.L. Jr., and Kennedy, A.R. "Levels of Proteolytic Activities as Intermediate Marker Endpoints in Oral Carcinogenesis". Cancer Epidemiology, Biomarkers and Prevention. 4(5):521-527, 1995.

16. **Clark, L.C.**, Alberts, D.S., "Selenium and Cancer: Risk or Protection?" (Editorial) Journal of the National Cancer Institute. 87(7):473-475, 1995.

17. Luo, X., Turnbull, B.W., Cai, II. and **Clark, L.C.** (1994). "Regression for censored survival data with lag effects." Communications in Statistics Ser. A. 23(12), 3417-3438.

18. Dinning, J.P., Hixon, L.J., **Clark, L.C.** "Prevalence Of Distal Colonic Neoplasia Associated With Proximal Colonic Cancers". Archives of Internal Medicine. 154:853-860, 1994.

19. Natarajan, R., Turnbull, B.W., Slate, E.H., Wells, M.T., **Clark, L.C.**, Abu-Libdeh, H. "A Computer Program for the Statistical Analysis of Repeated Event Data Using a Mixed Effects Regression Model." Computer Methods and Programs in Biomedicine. 42:283-294, 1994

20. **Clark, L.C.**, Hixson, L. J., Combs, Jr., G.F., Reid, M., Turnbull, B.W., Sampliner, R.E. "Plasma Selenium Concentration Predicts the Prevalence of Colorectal Adenomatous Polyps." Cancer Epidemiology, Biomarkers and Prevention. 2:41-46, 1993.

21. Luo, X., Turnbull, B.W., Cai, H., **Clark, L.C.** "Regression for Censored Survival Data with Lag Effects." Journal of Applied Statistical Science. 1:4 485-489, 1993

22. McShane, L.M., **Clark, L.C.**, Combs, G.F. and Turnbull, B.W. "Application of Variance Components Methods to Laboratory Quality for Biochemical Measurements." Proc. Biopharm. Sec. Amer. Statist. Assoc., Washington, D.C., 1993.

23. Waller, L.A., Turnbull, B.W., **Clark, L.C.**, Nasca, P. "Chronic Disease Surveillance and Testing of Clustering of Disease and Exposure: Application to Leukemia Incidence and TCE-Contaminated Dump sites in Upstate New York." Environmetrics. 1992;3(3): 281-300.

24. **Clark, L.C.**, Patterson, B.H., Weed, D.L., Turnbull, B.W. "Design Issues in Cancer Chemoprevention Trials Using Micronutrients: Application to Skin Cancer." Cancer Bulletin. 43: 519-24, November/December, 1991.

25. Vargas, P.A., Alberts, D.S., Ritenbaugh, C., Atwood, J.R., Sampliner, R., Earnest, D., Ramunujan, P., McGee, D., **Clark, L.C.**, Emerson, S. "Dietary Fiber and Colon Cancer Prevention." Cancer Bulletin. 43: 549-54, November/December, 1991.

26. McShane, L.M., **Clark, L.C.**, Combs, Jr., G.F., Turnbull, B.W. "Reporting the Accuracy of Biochemical Measurements for Epidemiologic and Nutrition Studies." American Journal of Clinical Nutrition. 3:1354-1360, 1991.

27. **Clark, L.C.**, Cantor, K.P. Allaway, W.H. "Selenium in Forage Crops and Cancer Mortality in U.S. Counties." Archives Environmental Health. 46(1):37-42, 1991.

28. Canfield, L.M., Hopkinson, J.M., Lima, A.S., Martin, G.S., Sugimoto, K., Burr, J., McGee, D.L., **Clark, L.C.** "Quantitation of Vitamin K in Human Milk." Lipids. 22:1-8, 1990.

29. Abu-Libdeh, H., Turnbull, B.W. and **Clark, L.C.** "Analysis of Multi-Type Recurrent Events in Longitudinal Studies: Application to a Skin Cancer Prevention Trial." Biometrics. 6:1017-1034, December, 1990.

30. Turnbull, B.W., Iwano, E.W., Burnett, W.S., Howe, H.L., **Clark, L.C.** "Monitoring for Clusters of Disease: Application to Leukemia Incidence in Upstate New York." American Journal of Epidemiology. Vol. 132, Supplement 1:S136-143, July, 1990.

31. Alberts, D.S., Einspahr, J., Rees-McGee, S., Ramanujam, P., Buller, M.K., **Clark, L.C.,** Ritenbaugh, C., Atwood, J., Pethigal, P., Earnest, D., Villar, H., Phelps, J., Lipkin, M., Wargovich, M. and Meyskens, Jr., F.L. "Effects of Dietary Fiber on Rectal Epithelial Cell Proliferation in Patients with Resected Colorectal Cancers." Journal National Cancer Institute. 82:15-21, August, 1990.

32. **Clark, L.C.** and Combs, Jr., G.F. "Selenium Compounds and the Prevention of Cancer: Research Needs and Public Health Implications." Journal of Nutrition. 116: 170-173 (1), 1986.

33. Chen, J. and **Clark, L.C.** "Proposed Supplemental Dosages of Selenium for a Phase I Trial Based on Dietary and Supplemental Selenium Intakes and Episodes of Chronic Selenosis" Journal of the American College of Toxicology. 5: 71-78, 1986.

34. **Clark, L.C.** "The Epidemiology of Selenium and Cancer." Fed. Proc. 44(9): 2584-2590, 1985.

35. Combs, G.F. and **Clark, L.C.** "Can Dietary Selenium Modify Cancer Risk?" Nutrition Reviews. 43: 325-331 (11), 1985.

36. **Clark, L.C.**, Graham, C.F., Crounse, R.J., Grimson, R., Hulka, B., and Shy, C.M. "Plasma Selenium and Skin Neoplasms: A Case Control Study." Nutr. Cancer. 6(1): 13-21, 1984.

37. Davenport, F., Hennessey, A., Masseb, H., **Clark, L.C.**, Abrams, G. and Mitchell, J. "Pilot Studies on Recombinate Cold Adapted Live Type A and B Influenza Virus Vaccines." Journal of Infectious Disease. 136(1): 17-25, 1976.

SUBMITTED MANUSCRIPTS

BOOK REVIEWS:

- **Clark, L.C.** "Progress and Perspectives in Chemoprevention of Cancer." G. DePalo, M.Sporn, U. Veronesi, eds. New York: Raven Press, 1992. 296pp., Ilus. Book review published in JNCI, 86: (1) p 57, 1994.

OTHER SCHOLARLY CONTRIBUTIONS:

COMMENTARIES:

- **Clark, L.C.** Commentary on "Interim Analyses: the Repeated Confidence Interval Approach" by Jennison, C., and Turnbull, B.W. Journal of the Royal Statistical Society. 51: 343 (3), 1989.

LETTERS TO THE EDITOR:

- **Clark, L.C.** and Jacobs, E.T. "Environmental Selenium and Cancer: Risk or Protection?" Cancer Epidemiology, Biomarkers & Prevention 7:847-848, 1998.
- JAMA
- Kamel, M.A., Ghaffar, Y.A., Wright, M. **Clark, L.C.,** Miller F.D. High HCV prevalence in Egyptian blood donors." Lancet. 340(8816):427, 1992.
- **Clark, L.C.** and Combs, Jr., G.F. Editorial reply to letter of Dr. Foster. Journal of Nutrition. 118: 238-239, 1988.
- **Clark, L.C.** and Portier, K.M. "Diethylstilbestrol and the Risk of Cancer." New England Journal of Medicine. 300: 263, 1979.

RESEARCH REPORTS:

1. **Clark, L.C.**, Guernsey de Zapien, J., Miester, J., and Mason T.E The Community Health Survey for Santa Cruz County: A Study of B-Lymphocyte Disorders. Tucson, AZ: University of Arizona, 1994.
2. Kramer, T.R., Noecker, R.J., Miller, J.M., Hutter, J.J., **Clark, L.C.** The histiocytoses of childhood: orbital involvement in Langerhans' cell histiocytoses. Tucson, AZ: University of Arizona, 1994.
3. Federer, W.T., **Clark, L.C.**, McDermott, N.M. and Robson, D.S. The Statistical Analyses of Ecological Data from the Cornell-China Diet and Cancer Project. Ithaca, NY: Cornell University, Biometrics Report Series, 1986.
4. Bondad, M., Candelaria, L., **Clark, L.C.**, Haaga, J.G., Haas, J., Henderson, C., Lisondra, F., Marks, G., Mason, J.B. and Test, K. Philippine National School Survey of Nutritional Status

Interim Report of Methods and Results from Region VI. Ithaca, NY: Cornell University, Nutritional Surveillance Program, 1984.

5. **Clark, L.C.** and Mason, J.B. Methodological and Analytical Issues in the Philippine National School Survey of Nutritional Status. Ithaca, NY: Cornell University, Nutritional Surveillance Program, 1983.

6. McKigney, J.L., **Clark, L.C.**, Olson, J.A. and Pettiss, S.T. Evaluation of the Vitamin A Deficiency Project. Office of Nutrition, Bureau for Science and Technology, Agency for International Development, 1988.

7. Federer, W.T., **Clark, L.C.** and Dubovi, E. A Surveillance and Control Program for Bovine Leukosis Based on Principles of Group Testing. Ithaca, NY Biometry Series 1987.

8. Federer, W.T., **Clark, L.C.** and Dubovi, E., A Surveillance and Sampling Program for the Identification of Blue Tongue Virus in Cattle. Ithaca, NY Biometry Series 1987.

PRESENTATIONS:

1. **Clark, L.C.,** "Prostate cancer -susceptibility markers," International Workshop on the Use of Biomarkers for Chemoprevention of Cancer The International Agency for Research on Cancer and the Deutsches Krebsforschungszentrum, with the support of the US National Institute of Environmental Health Sciences and the Deutsche Forschungsgemeinschaft. Heidelberg, Germany, Spring, 2000

2. **Clark, L.C.,** "Update: Selenium Prevention Trials," Nutritional Sciences - IDP Seminar Series, University of Arizona, September, 1999

3. **Clark, L.C.,** "1999 Cancer Conference, Meeting the Challenges of Comprehensive Cancer Control, Division of Cancer Prevention and Control, CDC, Atlanta, Georgia, September 9, 1999.

4. **Clark, L.C.,** Krongrad, A., Hollis, B., Carpenter, H.D., Borosso, C., Rounder, J.B., Jacobs, E.T., Witherton, R., Herlong, J.H., Janosko, E.O., Falk, S., "Selenium, Vitamin D, Melatonin, and Risk of Prostate Cancer," AUA Conference, Dallas, Texas, May, 1999

5. **Clark, L.C.,** "Selenium and Cancer Prevention," Committee on the Nutritional Sciences, University of Arizona, November, 1998-Invited.

6. **Clark, L.C.,** "Prevention of Cancer with Selenium," Grand Rounds, University of Colorado Cancer Center, September, 1998-Invited.

7. **Clark, LC**, "Selenium and Prevention of Prostate Cancer," US TOO International, Inc., Phoenix, Arizona, November, 1998.

8. **Clark, L.C.,** "Effects of the Trace Mineral Selenium on Prostate Cancer," International Conference on Quality of Life and Longevity Medicine, Brussels, Belgium, September, 1998

9. **Clark, L.C.,** "Decreased Incidence of Prostate Cancer with Selenium Supplementation," Satellite Symposium of the International Conference on Quality of Life and Longevity, Paris, France, September, 1998

10. **Clark, L.C.,** "Selenium: Un Role Spectaculaire Dans La Prevention Du Cancer," Press Conference for Pharma Nord, Paris, France, September, 1998.

11. **Clark, LC**, "Effects of Selenium on Cancer," Duluth Rotary Club, Duluth, MN, August, 1998
12. **Clark, LC,** "Nutritional Prevention of Cancer with Selenium:1983-93—The Results of the Randomized Trial." Moffitt Cancer Center, University of South Florida, Tampa, FL, August 1998.
13. **Clark, LC**, "Biomarkers for Establishing a UL for Selenium." Workshop on Dietary Antioxidants, National Academy of Sciences, Washington, D.C., July, 1998.
14. **Clark, LC,** "Nutritional Prevention of Cancer with Selenium:1983-93—The Results of the Randomized Trial." Moffitt Cancer Center, University of South Florida, Tampa, FL, June 1998.
15. **Clark, LC,** "Selenium Supplementation Decreases Cancer Incidence in a Randomized Cancer Prevention Trial." Selenium-Tellurium Developers Association (STDA) Symposium, Scottsdale, AZ, May 1998.
16. **Clark, LC,** "Decreased Incidence of Prostate Cancer with Selenium Supplementation," Critical Appraisal of Unconventional/Alternative Interventions for Carcinoma of the Prostate, US TOO International, Inc. The University of Chicago, Chicago, IL., May 1998
17. **Clark, LC,** "The Nutritional Prevention of Cancer with the Use of Selenium," FASEB Convention, Selenium Bionutrition II, April 1998, San Francisco, CA.
18. **Clark, LC,** "The Nutritional Prevention of Cancer with the Use of Selenium," 3rd Annual Symposium on Nutrition and Health, Harvard School of Public Health, March 1998, Boston, MA.
19. **Clark, LC,** "Whole Body Hypothermia:Another Option?" ICARE Prostate Cancer Symposium, March 1998, West Palm Beach, FL.
20. **Clark, LC,** "Selenium and Cancer Prevention," Cancer Biology Seminar Series, Arizona Cancer Center, University of Arizona, February 1998, Tucson, Arizona.
21. **Clark, LC,** "Reduced Incidence of Cancer in Patients Supplemented with Selenium: Results of a Randomized Clinical Trial," School of Biological Sciences Seminar, University of Surrey, January 1998, Surrey, United Kingdom.
22. **Clark, LC,** "Selenium and Cancer Prevention," Chemical and Biological Sciences, University of Arizona, November 1997.
23. **Clark, LC,** "Selenium Supplementation and Cancer Prevention: A Randomized Trial." 4th International Symposium on Nutrition in Cancer, October 1997, New Orleans, LA.
24. **Clark, LC,** "Selenium and Cancer Prevention." ACAM's Fall Convention, October 1997, Anaheim, CA.
25. **Clark, LC,** "Selenium Supplementation and Cancer Prevention: A Randomized Trial." Nutracon '97, 4th Annual Conference on Maximizing Scientific and Marketing Opportunities for Nutraceuticals, Dietary Supplements, Functional & Medical, July 1997, Las Vegas, NV.
26. **Clark LC.** "Cancer Prevention by Selenium." Symposium on Dietary Factors in Cancer Prevention: Molecular Mechanisms and Applications, June 1997, Rutgers University, N.J.
27. **Clark LC.** "Micronutrients and Prostate Cancer." Micronutrients and Human Cancer Risk, Prospects for Prevention, May 1997, Aarhus, Denmark.
28. **Clark LC,** Combs Jr GF, Turnbull BW, Slate EH and the Nutritional Prevention of Cancer Research Group. "Effects of Selenium Supplementation for Cancer Prevention in Patients with Carcinoma of the Skin: A Randomized Clinical Trial 1983-93. AACR, April 1997, San Diego,

CA.

29. **Clark LC,** Combs Jr GF, Turnbull BW, Slate EH. "Effect of Selenium Supplementation for Cancer Prevention 1983-1996: A Randomized Clinical Trial." FASEB, April 1997, New Orleans, LA.

30. **Clark, LC,** "The Nutritional Prevention of Cancer with Selenium: Results of a Cancer Prevention Trial," University of Pennsylvania Medical Center, April 1997, Philadelphia, PA.

31. **Clark, L.C.** "Decreased Incidence of Prostate Cancer in Patients with Prior Carcinoma of the Skin," 7th International Prostate Cancer Update, Beaver Creek, Colorado; January 1997.

32. **Clark, L.C.**, Powis, G., McCarty, M. "Selenium and Cancer," Arizona Cancer Center Workshop, Tucson, Arizona; December 1996.

33. **Clark, L.C.** "Effects of Selenium Supplementation for Cancer Prevention in Patients with Carcinoma of the Skin: A Randomized Trial." Cancer Prevention Program Presentation, Arizona Cancer Center; November 1996.

34. **Clark, L.C.** "Selenium Chemoprevention" University of Hawaii, Cancer Research Center, Honolulu, Hawaii, October 1996.

35. **Clark, L.C.** Council for Responsible Nutrition's Annual Meeting, "Selenium Supplementation Decreases Cancer Risk," September, 1996, Amelia Island, Florida.

36. **Clark, L.C.** Safety Monitoring and Advisory Committee Teleconference Meeting for the Nutritional Prevention of Cancer Project. Tucson, Arizona, February, 1994; Tucson, Arizona, December, 1994

37. **Clark, L.C.** "Antioxidants and Cancer Prevention." American Dietetic Association's 77th Annual Meeting and Exhibition, Orlando, Florida; October 1994.

38. **Clark, L.C.** Safety Monitoring Committee Meeting for the Nutritional Prevention of Skin Cancer Project. Ithaca, New York at Cornell University, March, 1988; August, 1989; November, 1989; October, 1990; December, 1991; July, 1992; June, 1993; June, 1994.

39. **Clark, L.C.** "The Role of Biomarkers in Field Studies of Environmentally Associated Cancers." Atlanta, Georgia, May, 1994.

40. **Clark, L.C.** "Cancer Prevention Trials with Selenium: The 10 Year Experience." Cancer Biology Seminar Series, Arizona Cancer Center, Tucson, Arizona January, 1994.

41. **Clark, L.C.**, Reid, M.E. Clinical Coordinator's Workshop, Nutritional Prevention of Skin Cancer. April, 1987, Charleston, South Carolina; June, 1988, Columbia, South Carolina, June, 1989, Columbia, South Carolina, June, 1990, Columbia, South Carolina, June, 1991, Columbia, South Carolina, March, 1992, Columbia, South Carolina, October, 1993, Wrightsville Beach, North Carolina.

42. **Clark, L.C.**, Reid, M.E. Clinical Coordinator's Meeting, Nutritional Prevention of Cancer, Full Day Meeting. September, 1988, Atlanta, Georgia; Columbia, South Carolina, April, 1990; June, 1991; April, 1992; Wilmington, North Carolina, September/October 1993.

43. **Clark, L.C.** "Nutritional Prevention of Cancer, Current Perspectives, Future Directions." Ann Arbor, Michigan, October, 1993.

44. **Clark, L.C.** "The Status of Selenium Compounds for Cancer Chemoprevention Trials." NCI September, 1993.**Clark, L.C.** "The Prevalence of Colorectal Adenomatous Polyps is Higher in Patients with Low Plasma Selenium Levels." Berlin, Germany; April, 1993.

45. **Clark, L.C.** "The First Generation of Cancer Prevention Trials: Lessons, Results, and Directions for the Future." American Society of Preventative Oncology Conference, March, 1993.

46. **Clark, L.C.** "Low Plasma Selenium Predicts the Prevalence of Colorectal Adenomatous Polyps in a Cancer Prevention Trial." Federation of American Societies for Experimental Biology, April 1993.

47. **Clark, L.C.** "Low Plasma Selenium (Se) Predicts the 24 Month Incidence of Squamous Cell Carcinoma of the Skin in a Cancer Prevention Trial." Federation of American Societies for Experimental Biology, April 1993.

48. **Clark, L.C.**, Reid, M.E. Clinical Investigator's Annual Nutritional Prevention of Cancer Project. December, 1988, Washington, D.C., December, 1989, San Francisco, California, December, 1990, Atlanta, Georgia, December 1991, Dallas, Texas, December 1992, Washington, D.C., December, 1993, New Orleans, Louisiana, February, 1995.

49. **Clark, L.C.**, Reid, M.E. Clinical Director's Meeting and Workshop Nutritional Prevention of Skin Cancer Project at the American Academy of Dermatology, San Antonio, Texas, December, 1987; Washington D.C., December, 1988; San Francisco, CA, December, 1989; Atlanta, GA, December, 1990; Houston, TX, December, 1991; San Francisco, CA, December, 1992.

50. **Clark, L.C.** "Inverse Association of Plasma Selenium Concentration and Incidence of Colorectal Neoplastic Polyps in Americans." The Fifth International Symposium on Selenium in Biology and Medicine, July, 1992.

51. **Clark, L.C.** "The Design of Secondary & Tertiary Cancer Prevention: An Epidemiological Perspective." The IVth International Conference on Prevention of Human Cancer: Nutrition & Chemoprevention Controversies, Arizona Cancer Center, Tucson, Arizona, June, 1992.

52. **Clark, L.C.** "The Nutritional Prevention of Skin Cancer in Double Blind Clinical Trial." University of Miami School of Medicine, November, 1991.

53. **Clark, L.C.** "Plasma Selenium Predicts the Risk of Neoplastic Polyps in a Double Blind Clinical Trial." NCI, 1991, DCPC seminar.

54. **Clark, L.C.** "Diet/Nutrition and Cancer: Fact and Fiction." Presented at the ACS Cancer Update Program, University of New Mexico, Albuquerque, NM, October, 1990.

55. **Clark, L.C.** "Opportunities for the Prevention of Melanoma Skin Cancer." Presented at the AMC Cancer Research Center, Denver, Colorado, October, 1990.

56. **Clark, L.C.** "Epidemiology of Micronutrients and Cancer." Presented at the National Cancer Institute, Cancer Prevention and Control Academic Course, Washington D.C., November, 1989.

57. **Clark, L.C.** "Cancer Prevention-Current Perspectives." Presented at Medical Grand Rounds, Martinez VA Medical Center, Martinez, California, June, 1989 (3 lectures).

58. **Clark, L.C.** Trial Investigator Workshop, "Selenium as a Chemopreventive Agent." NCI Invited Seminar, Rockville, Maryland, December, 1988.

59. **Clark, L.C.** "Selenium and Cancer: A Current Perspective." Presented at the 2nd International Conference of Anticancer Research, Saronis, Greece, October, 1988.

60. **Clark, L.C.** "Selenium as a Chemopreventive Agent." University of Arizona, College of Medicine, Tucson, Arizona, June, 1988.

61. **Clark, L.C.** "An Overview of Diet and Cancer." Invited address sponsored by the American Cancer Society and Area L Health Education Center, Wilson, NC, May, 1988.

62. Graham, G. and **Clark, L.C.** "A Prospective Cohort Study of Plasma Selenium and Non-Melanoma Skin Cancer." Presented at the North American Clinical Dermatology meeting in Portugal, April, 1988.

63. Allison, Jr. R., and **Clark, L.C.** "An Overview of a Double Blind Clinical Trial for the Prevention of Non-Melanoma Skin Cancer with Nutritional Supplement of Selenium." Presented at the North American Clinical Dermatology meeting in Portugal, April, 1988.

64. **Clark, L.C.** "The Epidemiology of Skin Cancer." Invited address, delivered at the Valley of the Sun Dermatology Conference, Scottsdale, Arizona, 1988.

65. Turnbull, B. and **Clark, L.C.** "Some New Approaches to Clustering Methodology: Application to Leukemia Incidence in Upstate New York." Invited address, delivered at the Division of Chronic Disease, Center for Disease Control, Atlanta, GA, 1988.

66. **Clark, L.C.** "Effect of Micronutrients on Cancer Risks." Invited address, delivered at the Grand Medical Rounds Interfaith Medical Center, Brooklyn, New York, 1988.

67. **Clark, L.C.** "Prevention of Primary Liver Cancer with a Nutritional Supplement of Selenium: A Pilot Study." Presented at the Third International Conference on the Prevention of Human Cancer: Chemoprevention, Tucson, Arizona, January, 1988.

68. Abu-Libdeh, H., **Clark, L.C.** and Turnbull, B.W. "Statistical Modeling and Analysis of Multiple Events of Skin Cancer in a Controlled Clinical Trial." Presented at the Third International Conference on the Prevention of Human Cancer: Chemoprevention, Tucson, Arizona, January, 1987.

69. McShane, L., **Clark, L.C.** and Turnbull, B.W. "Quality Control Procedure for High Pressure Liquid Chromatographic Analysis of Plasma Vitamin E." Presented at the Third International Conference on the Prevention of Human Cancer: Chemoprevention, Tucson, Arizona, January, 1987.

70. **Clark, L.C.** "Implications of Epidemiologic Studies for Ongoing Clinical Trials of Selenium and Selenium Enriched Yeast." Invited address, delivered at the NCI Workshop on Strategies Needed to Develop Selenium Compounds of Chemopreventive Agents, Bethesda, Maryland, 1985.

71. **Clark, L.C.** "The Epidemiology of Selenium and Cancer." Invited address, delivered at the Symposium on Selenium, Federation of American Societies of Experimental Biology, St. Louis, Missouri, 1984.

72. **Clark, L.C.** "Conference on Public Policy: Diet and Cancer." Co-Chairman of Risk Assessment Section, Ithaca, New York, 1982.

73. **Clark, L.C.**, Graham, G.F., Crounse, R., Grimson, R. and Shy, C.M. "A Case Control Study of Skin Cancer and Selenium in Eastern North Carolina." Presented at American Public Health Association, Montreal, Canada, 1982.

74. **Clark, L.C.**, Graham, G.F. and Crounse, R.G. "Selenium, Arsenical Keratoses and Skin Cancer in Eastern North Carolina." Presented at the Society for Environmental Geochemistry and Health, Greenville, North Carolina, 1982.

75. **Clark, L.C.**, Shy, C.M. and Portier, K.M. "Cancer Mortality and Agricultural Activity: An Association with Cotton Production and Large Farms in the Southeastern U.S." Presented at Society of Epidemiologic Research, Iowa City, Iowa, 1978.

76. Shy, C.M., **Clark, L.C.** and Most, B.M. "Atmospheric Carcinogens and Lung Cancer in the U.S." Presented at American Public Health Association, Washington, D.C., 1977.

77. **Clark, L.C.**, Shy, C.M. and Most, B.M. "Cancer Mortality and Pesticide Use in Selected Regions on the U.S." Presented at International Epidemiologic Association Meeting, San Juan, Puerto Rico, 1977.

ORGANIZED WORKSHOPS:

- **Clark, L.C.,** "PRECISE, Prevention of Cancer with Selenium," International Workshop. Conducted at the Danish Cancer Society in Copenhagen, Denmark, September, 1999
- **Clark, L.C.** "Selenium and Prostate Cancer", AUA Convention, Dallas, Texas, May, 1999.
- **Clark, L.C.,** "Changing the World with Selenium," PRECISE International Workshop III, Danish Cancer Society, Copenhagen, Denmark, September, 1998.
- **Clark, L.C.** "Selenium for Cancer Prevention in Europe and America Workshop II." Conducted at the Danish Cancer Society in Copenhagen, Denmark, January 16-18, 1998.
- **Clark, L.C.** "A Seven Country Study: Selenium for Cancer Prevention in Europe and America" Workshop. Conducted at the Danish Cancer Society in Copenhagen, Denmark, September 18-21, 1997.

RESEARCH SUPPORT

GRANTS / CONTRACTS CURRENTLY FUNDED AS PRINCIPAL INVESTIGATOR:

- The Nutritional Prevention of Cancer. **Larry C. Clark**, P.I. Funded by the National Cancer Institute 5/1/99-4/30/02, Total direct amount for 3 years, $1,750,203.

- Phase II Chemoprevention Trials of Selenium and Prostate Cancer – "Watchful Waiting Trial", **Larry C. Clark**, P.I. Funded by the National Cancer Institute, 09/01/98-08/31/03, Total amount funded for five years, $3,957,181.

- Chemoprevention Trial of Selenium and Prostate Cancer, **Larry C. Clark**, P.I. Funded by the U.S. Army Medical Research and Materiel Command DOD Prostate Cancer Research Program 10/01/98-09/30/03, Total amount funded for five years $482,008.

- Phase III Trial of Selenium for Prostate Cancer Prevention – "Negative Biopsy Trial" **Larry C. Clark**,

P.I. Funded by the National Cancer Institute, 07/01/99-6/30/04 Total amount funded for five years $4,620,937.

PREVIOUSLY FUNDED GRANTS/CONTRACTS:

- Prevention of Non-Melanoma Skin Cancer with a Nutritional Supplement of Selenium. **Larry C. Clark**, P.I. Funded by the National Cancer Institute, 8/15/88-11/30/98, Total direct amount for 5 years, $4,375,000.
- PSA as An Intermediate Marker of Prostate Cancer, **Larry C. Clark**, P.I. Funded by the National Cancer Institute, 7/1/93-6/30/96, Total three year direct cost amount $894,000.
- Health Survey of Santa Cruz County: A Study of B-Lymphocytes Disorders. Funded by the Arizona State Department of Health 1/1/94-12/31/94. Total direct amount $110,000.
- Prevention of Non-Melanoma Skin Cancer. Funded by the American Institute of Cancer Research, **Larry Clark**, P.I., 1/1/89-12/31/90. Total direct amount $110,000.
- Prevention of Cancer with Selenium in the People's Republic of China. (**L. Clark**, P.I.) Funded by AICR ($110,500, 5/1/84-4/30/86).
- The Prevention of Non-Melanoma Skin Cancer with a Nutritional Supplement of Selenium. Funded by AICR (Total Budget, $110,000, 1/1/85-12/31/87).
- Colon Cancer Prevention Project. Funded by the National Cancer Institute. David Alberts, P.I., **Larry Clark**, Investigator (10%), Total annual amount $1,500,000, 7/1/89-6/30/90.
- The Wilson Skin Cancer Cohort Project. Partial funding from the North Carolina Yam Commission ($2,000, June 1, 1983).
- Pilot Study for the Nutritional Prevention of Squamous Cell Carcinoma. Funded by Nutrition 21 ($15,000, May 1, 1983).

PREVIOIUSLY FUNDED GRANTS AS CO-INVESTIGATOR:

- Cancer Etiology and Prevention Training Grant. The National Cancer Institute. Thomas Moon, P.I., **Larry Clark**, Co-investigator (5%), 6/1/90-5/30/95, Total annual amount $79,740.
- Colon Cancer Prevention Program Project. The National Cancer Institute. David Alberts, P.I., **Larry Clark**, Investigator (7.5%), 7/1/90-6/30/95, Total annual amount $1,500,000.
- Navajo Infant feeding study and morbidity study, Anne Wright, P.I., **Larry Clark**, Investigator (5%), 7/1/93 - 12/31/95, Total amount $152,123.
- Five a day: Healthier Eating for the Overlooked Worker, David Buller, P.I., **Larry Clark**, Investigator, (1%), 4/1/93-3/31/97, Total amount $1,597,899.

SERVICE - UNIVERSITY OF ARIZONA COMMITTEES

1995 Arizona Cancer Center Deputy Director Search Committee
Arizona Cancer Center Molecular Epidemiologist Search Committee Executive Committee, Epidemiology Graduate Program
Committee on Nutrition

1994 Committee on Nutrition
Executive Committee, Epidemiology Graduate Program

1993 Epidemiology and Biometry Section Curriculum Consultant
Executive Committee, Epidemiology Graduate Program
Family and Community Medicine Finance Committee
Graduate Program in Public Health Planning Committee

1992 Epidemiology and Biometry Section Curriculum Consultant
Executive Committee Epidemiology Graduate Program
Family and Community Medicine Finance Committee
Graduate Program in Public Health Planning Committee
International Health Steering Committee
Medical Student Research Committee

1991 Epidemiology and Biometry Section Curriculum Consultant
Executive Committee, Epidemiology Graduate Program
Family and Community Medicine Finance Committee
Graduate Program in Public Health Planning Committee
International Health Steering Committee
Medical Student Research Committee

1990 Allied Health Professions Department Chair Search Committee
College of Agriculture Research Review Committee
Epidemiology and Biometry Section Curriculum Consultant
Executive Committee, Epidemiology Graduate Program
Family and Community Medicine Finance Committee
Family and Community Medicine Academic Self-Study Committee
Graduate Program in Public Health Planning Committee
International Health Steering Committee
Medical Student Research Committee

1989 Allied Health Professions Department Chair Search Committee
Arizona Cancer Center Biometry Assistant Professor Search Committee
Executive Committee, Epidemiology Graduate Program
Family and Community Medicine Academic Self-Study Committee
International Health Steering Committee

Curriculum Vita

James Roger Marshall, Ph.D.

Education

B.A. Political Science: California State University, Long Beach, 1968
M.A. Behavioral Science: California State, Dominguez Hills, 1972
M.A. Sociology: University of California at Los Angeles, 1974
Ph.D. Sociology: University of California at Los Angeles, 1977;
"Temporal Variation in Suicide: The United States: 1933-1972," Leo G. Reeder, Chair.

Employment

1996-
1997- Professor of Public Health
Associate Director of Cancer Prevention and Control
Arizona Cancer Center
University of Arizona, College of Medicine
1515 N. Campbell Avenue, Tucson, Arizona 85724
(520) 626-4768
(520) 626-5348

1991-1996 Professor, Department of Social and Preventive Medicine
School of Medicine and Biomedical Sciences
State University of New York at Buffalo

1993-1996 Senior Associate Research Scientist
Research Institute on Addictions, Buffalo, New York

1994-1996 Adjunct Professor, Nutrition Program
School of Health Related Professions
State University of New York at Buffalo

1991-1994 Research Associate Professor, Nutrition Program
School of Health Related Professions
State University of New York at Buffalo

1983-1991 Associate Professor, Department of Social and Preventive Medicine
School of Medicine
State University of New York at Buffalo

1981-1983 Assistant Professor, Department of Social and Preventive Medicine
School of Medicine
State University of New York at Buffalo

1981-present Assistant Research Professor
Department of Experimental Pathology/Epidemiology

Roswell Park Cancer Institute, Graduate Division, Buffalo, New York

1977-1981 Assistant Professor, Department of Sociology
State University of New York at Buffalo

1976-1977 Research Analyst, Division of Research in Medical Education
University of Southern California School of Medicine

Honors and Awards

1992 Commendation for Teaching Excellence
SUNY at Buffalo School of Medicine and Biomedical Sciences

1994 Commendation for Teaching Excellence
SUNY at Buffalo School of Medicine and Biomedical Sciences

1995 American Medical Women's Association: Gender Equity Award
SUNY at Buffalo School of Medicine and Biomedical Sciences

1996 Commendation for Teaching Excellence
SUNY at Buffalo School of Medicine and Biomedical Sciences

Memberships

American Epidemiologic Society
Society for Epidemiologic Research
American Association for Cancer Research
American Society for Nutritional Sciences
American Association for Cancer Education
American Society of Preventive Oncology

Editorial Service

American Journal of Public Health
Epidemiology
Gastroenterology
HMO Practice
Journal of the American Medical Association
Journal of the National Cancer Institute
New England Journal of Medicine
Nutrition and Cancer
Statistics in Medicine
Cancer Causes and Control

1983-1996 Consulting Editor, Journal of Suicide and Life-Threatening Behavior
1987-1998 Associate Editor, American Journal of Epidemiology
1998 Associate Editor, Cancer Epidemiology, Biomarkers and Prevention

Grants and Contracts

Current Research

Active

1 R25 CA78447-01 (Marshall)	07/01/98-06/30/03	15%
NIH/NCI	$2,744,232	
Cancer Prevention and Control Training Grant		

The goal of this project is to continue the precedence of comprehensive training offered by the Cancer Prevention and Control Program established at the Arizona Cancer Center.

CA23074 NIH	07/01/98-06/30/03	10%
Cancer Center Support Grant	$80,940	
Project: Behavioral Measurement Shared Service (Marshall)		

This is a service core, providing questionnaire processing and data analysis, in the Arizona Cancer Center

UCSD (Marshall)	12/01/97-11/30/02	8%
Women's Healthy Eating Study (WHEL)	$865,684	

This is a randomized trial, evaluating diet change as a means of preventing breast cancer recurrence.

CA41108 (PI: David Alberts)	05/01/95-04/30/00	6%
NCI	$2,131,170	
Colon Cancer Prevention Program Project		

This is an integrated program project incorporating two randomized trials and an epidemiologic analysis of predictions of genetic mutations in adenomatous polyps.

ADHS 85025 (PI: J. Marshall)	10/01/97-09/30/99	3%
Arizona Dept. of Health Services	$214,000	
Well Women Screening and Prevention Project		

This project will institute and evaluate a prospective trial of physical activity among post menopausal Hispanic women at high risk for chronic disease.

ADHS 85026 (PI: J. Marshall)	10/01/97-09/30/99	3%
Arizona Dept. of Health Services	$148,200	
Well Women Screening and Prevention Project		
Amendment #5 - Blood Analysis		

The purpose of this project is to determine the levels of certain nutrients within the blood.

ADHS 85027 (PI: J. Marshall)	10/01/97-09/30/99	0%
Arizona Dept. of Health Services	$57,170	

Well Women Screening and Prevention Project
Amendment #6 - Promotoras

The purpose of this project is to educate urban women in Maricopa County regarding the availability of screening, diagnosis, follow-up, and treatment options for the prevention of breast and cervical cancer.

1 U01CA74799-01 (PI: J. Marshall)	07/01/97-06/30/01	15%
NIH/NCI	$128,789	
Colon Cancer Family Registry		

The goal of this project is to establish a population based familial colon cancer registry using the Cancer Registry data bases of Colorado and Arizona as the ascertainment source for index cases.

1 U01 CA77178-01A1 (PI: J. Marshall)	12/01/98-11/30/03	30%
NIH/NCI	$5,433,647	
Selenium-based Chemoprevention among HGPIN Patients		

Invited Presentations

Speaker; Industrial Epidemiology Forum, Quality Control and Assurance in Epidemiologic Research, Salt Lake City, Utah, 1990.

Speaker; International Cancer Congress: An International Perspective on Diet, Nutrition and Cancer; Hamburg, Federal Republic of Germany, 1990.

Guest Lecturer, Memorial Sloan-Kettering Cancer Center, 1992.

Guest Lecturer, University of Minnesota School of Public Health, 1992.

Speaker; Fourth International Conference on the Prevention of Human Cancer: Nutrition and Chemoprevention Controversies; Arizona Cancer Center, Tucson, AZ, 1992.

Lecturer; American Cancer Society, Workshop on Nutrition and Cancer, 1992.

Faculty Speaker; Second International Conference on Dietary Assessment Methods, Boston, MA, 1995.

Third International Conference on Dietary Assessment Methods, Papendal, Arnhem, The Netherlands, May 6-9, 1998.

Charles Rasco III Symposium on Colorectal Cancer, Walton Auditorium, Arkansas Cancer Research Center, University of Arkansas College of Medicine, Little Rock, Arkansas, June 20, 1998.

"Future Strategies for the Medical Prevention of CRC" at Falk Symposium Colorectal Cancer: Molecular Mechanisms, Premalignant State and its Prevention, Titisee, Germany, October 14-15, 1998.

Vahouney Satellite Symposium on "Dietary Fibre in Health and Disease", Nutrition Society of Australia and the Australasian Clinical Nutrition Society, Adelaide, Australia, November 29 to December 2, 1998.

"Cancer Prevention: Of Course. How?" to Leadership Summit, American Cancer Society, Phoenix, Arizona, August 28, 1999.

Book Chapters

1. **Marshall J**, Graham S. Cancer. In: Applications of Social Science to Clinical Medicine and Health Policy. New Brunswick NJ: Rutgers University Press 1986, 157-174.

2. **Marshall JR**, Funch DP. Gender and illness behavior among colorectal cancer patients. In: Women and Cancer. New York: The Haworth Press 1987, 67-82.

3. Martinez ME, **Marshall JR**, Alberts DS. Dietary fiber, carbohydrates, and cancer. In: Nutritional Oncology. Academic Press 1999, 185-194.

4. **Marshall JR**, Alberts DS. Future strategies for the medical prevention of colorectal cancer. In. Colorectal Cancer Molecular Mechanisms, Premalignant State and its Prevention. (Schmiegel W, Scholmerich J, Eds). Hingham, Massachusetts: Kluwer Academic Publishers BV, 1999.

Publications in Refereed Journals

1. **Marshall J**. Changes in white male suicide: 1948-1972. J Gerontol 33: 763-768, 1978.
2. **Marshall J**, Funch D. Mental illness and the economy: A critique and partial replication. J Health Soc Behav 20: 282-289, 1979.
3. **Marshall J**. Stress, strain, and coping. J Health Soc Behav 20: 200-201, 1979.
4. **Marshall J**, Priore R, Haughey B, Rzepka T, Graham S. Spouse-subject interviews and the reliability of diet studies. Am J Epidemiol 112: 675-683, 1980.
5. **Marshall J**. Political Integration and the effect of war on suicide: The United States, 1933-1976. Social Forces 59:771-785, 1981.
6. **Marshall J**, Priore R, Graham S, Brasure J. On the distortion of risk estimates in multiple exposure level case control studies. Am J Epidemiol 113: 464-473, 1981.
7. Graham S, Mettlin C, **Marshall J**. Dietary factors in the epidemiology of cancer of the larynx. Am J Epidemiol 113: 675-680, 1981.
8. Mettlin C, Graham S, Priore R, **Marshall J**, Swanson M. Diet and cancer of the esophagus. Nutr Cancer 2: 143-147, 1981.
9. Funch D, **Marshall J**. Patient attitudes following participation in a health outcome survey. Am J Public Health 71: 1396-1398, 1981.

10. **Marshall J**, Hodge R. Durkheim and Pierce on suicide and economic change. Social Science Research 10: 101-114, 1981.
11. **Marshall J**, Dowdall G. Employment and mental hospitalization: The case of Buffalo, New York, 1914-1955. Social Forces 60: 843, 1982.
12. Graham S, **Marshall J**, Mettlin C, Rzepka T. Diet in the epidemiology of breast cancer. Am J Epidemiol 116: 68-75, 1982.
13. **Marshall J**, Graham S, Swanson M. Caffeine consumption and benign breast disease: A case-control comparison. Am J Public Health 72: 610-612, 1982.
14. **Marshall J**, Graham S, Mettlin C, Shedd D, Swanson M. Diet in the epidemiology of oral cancer. Nutr Cancer 3: 145-149, 1982.
15. **Marshall J**, Gregorio D, Walsh D. Sex differences in illness behavior: Care seeking among cancer patients. J Health Soc Behav 23: 197-204, 1982.
16. Funch D, **Marshall J**. The role of stress, social support and age in survival from breast cancer. J Psychosom Res 27: 77-83, 1983.
17. **Marshall J**, Burnette W, Brasure J. On precipitating factors: Cancer as a cause of suicide. Suicide Life Threat Behav 13: 15-27, 1983.
18. **Marshall J**, Funch D. Social environment and breast cancer: A cohort analysis of patient survival. Cancer 52: 1546-1550, 1983.
19. Violanti J, **Marshall J**, Howe B. Police occupational demands, psychological distress and the coping function of alcohol. J Occup Med 25: 455-458, 1983.
20. **Marshall J**, Graham S, Byers T, Swanson M, Brasure J. Diet and smoking in the epidemiology of cancer of the cervix. J Natl Cancer Inst 70: 847-851, 1983.
21. Graham S, Haughey B, **Marshall J**, Priore R, Byers T, Rzepka T, Mettlin C, Pontes JE. Diet in the epidemiology of carcinoma of the prostate. J Natl Cancer Inst 70: 687-692,1983.
22. Byers T, **Marshall J**, Graham S, Mettlin C, Swanson M. A case-control study of dietary and nondietary factors in ovarian cancer. J Natl Cancer Inst 71: 681-686, 1983.
23. Byers T, Rosenthal R, **Marshall J**, Rzpeka T, Cummings M, Graham S. Dietary history from the distant past: A methodological study. Nutr Cancer 5: 69-77, 1983.
24. **Marshall J**, Graham S. Use of dual responses to increase validity of case-control studies. J Chronic Dis 37(2): 125-136, 1984.
25. Funch D, **Marshall J**. Self-reliance as a modifier of the effects of life, stress, and social support. J Psychosom Res 28: 9-15, 1984.
26. Haughey B, **Marshall J**, Mettlin C, Nemoto T, Kroldart K, Swanson M. Nurses' ability to detect nodules in silicone breast models. Oncol Nurs Forum 11: 37-42, 1984.
27. Gregorio D, **Marshall J**. Fine tuning well being: Food stamp use and nutritional adequacy of children's diets. Social Science Quarterly, December: 1137-1146, 1984.
28. Funch D, **Marshall J**. Measuring life stress: Factors affecting fall-off in the reporting of life events. J Health Soc Behav 25: 453-464, 1984.
29. Byers T, Graham S, Rzepka T, **Marshall J**. Lactation and breast cancer: Evidence for a negative association in premenopausal women. Am J Epidemiol 121: 664-674, 1985.
30. Gregorio D, **Marshall J**, Zielezny M. Fluctuations in relative odds ratios due to variance differences in case-control studies. Am J Epidemiol 121: 767-774, 1985.
31. Byers T, **Marshall J**, Fiedler R, Zielezny M, Graham S. Assessing nutrient intake with an abbreviated dietary interview. Am J Epidemiol 122: 41-50, 1985.
32. Gregorio D, Emrich L, Graham S, **Marshall J**, Nemoto T. Dietary fat consumption and survival among women with breast cancer. J Natl Cancer Inst 75: 37-39, 1985.

33. Assaf AR, Cummings KM, Graham S, Mettlin C, **Marshall J**. Comparison of the three methods of teaching women how to perform breast self-examination. Health Educ Q 12: 259-272, 1985.
34. Graham S, **Marshall J**, Haughey B, Stoll H, Zielezny M, Brasure J, West D. An inquiry into the epidemiology of melanoma. Am J Epidemiol 122: 606-619, 1985.
35. Middleton B, Byers T, **Marshall J**, Zielezny M, Graham S. Dietary vitamin A and cancer – A multi-site case-control study. Nutr Cancer 8: 107-116, 1986.
36. Violanti J, Vena J, **Marshall J**. Disease risk and mortality among police officers: New evidence and contributing factors. J Police Sci Admin 14: 17-23, 1986.
37. Vena J, Violanti J, **Marshall J**. Mortality of a municipal worker cohort: III Police officers. Am J Ind Med 10:383-397, 1986.
38. Funch D, **Marshall J**, Gebhardt G. Assessment of a short scale to measure social support. Soc Sci Med 23: 337-344, 1986.
39. Byers T, Graham S, Haughey B, **Marshall J**, Swanson M. Diet and lung cancer risk: Findings from the Western New York diet study. Am J Epidemiol 125: 351-363, 1987.
40. Byers T, **Marshall J**, Anthony E, Fiedler R, Zielezny M. The reliability of dietary history from the distant past. Am J Epidemiol 125: 999-1011, 1987.
41. **Marshall J**. The reliability and validity of dietary data as used in epidemiology. Cancer Surv 6: 673-683, 1987.
42. Graham S, **Marshall J**, Haughey B, Mittelman A, Swanson M, Zielezny M, Byers T, Wilkinson G, West D. Dietary epidemiology of cancer of the colon in Western New York. Am J Epidemiol 128: 490-503, 1988.
43. Haughey B, **Marshall J**, Nemoto T, Kroldart K, Mettlin C, Swanson M. Breast-self examination: Reported practices, proficiency and stage of breast cancer at diagnosis. Oncol Nurs Forum 15: 315-319, 1988.
44. Dlugosz LJ, Byers T, Msall ME, **Marshall J**, Lesswing A, Cooke RE. Relationships between laterality of congenital upper limb reduction defects and school performance. Clin Pediatr 27: 319-324, 1988.
45. Freudenheim J, **Marshall J**. The problem of profound mismeasurement and the power of epidemiologic studies of diet and cancer. Nutr Cancer 11: 243-250, 1988.
46. **Marshall J**. The use of dual or multiple reports in epidemiologic studies. Stat Med 8: 1041-1049, 1989.
47. Cummings KM, Markello SJ, Mahoney M, McElroy P, Bhargava A, **Marshall JR**. Measurement of lifetime exposure to passive smoke. Am J Epidemiol 130: 122-132, 1989.
48. Randall E, **Marshall J**, Graham S, Brasure J. Frequency of food use data and the ultidimensionality of diet. J Am Diet Assoc 89: 1070-1075, 1989.
49. Duffy LC, Zielezny MA, Riepenhoff-Talty M, Byers TE, **Marshall J**, Weiser MM, Graham S, Ogra PL. Vasoactive intestinal peptide as a laboratory supplement to a clinical activity index in Inflammatory bowel disease. Dig Dis Sci 34: 1528-1535, 1989.
50. Cummings KM, Markello SJ, Mahoney M, Bhargava AK, McElroy PD, **Marshall JR**. Measurement of current exposure to environmental tobacco smoke. Arch Environ Health 45: 74-79, 1990.
51. **Marshall J**. Data dredging and noteworthiness. Epidemiology, 1:5-7, 1990.
52. Graham S, Haughey B, **Marshall J**, Brasure J, Zielezny M, Freudenheim J, West D, Nolan J, Wilkinson G. Diet in the epidemiology of gastric cancer. Nutr Cancer 13: 19-34, 1990.

53. Freudenheim J, Graham S, **Marshall J**, Haughey B, Wilkinson G. Lifetime alcohol intake and risk of rectal cancer in Western New York. Nutr Cancer 13:101-109, 1990.
54. Skretny MT, Cummings KM, Sciandra R, **Marshall J**. An intervention to reduce the sale of cigarettes to minors. NY State J Med 90: 54-55, 1990.
55. Graham S, **Marshall J**, Haughey B, Brasure J, Freudenheim J, Zielezny M, Wilkinson G, Nolan J. Nutritional epidemiology of cancer of the esophagus. Am J Epidemiol 131: 454-467, 1990.
56. Freudenheim J, Graham S, **Marshall J**, Haughey B, Wilkinson G. A case-control study of diet and rectal cancer in Western New York. Am J Epidemiol 131: 612-624, 1990.
57. Duffy LC, Zielezny MA, **Marshall JR**, Weiser MM, Byers TE, Phillips JF, Ogra PL, Graham S. Cigarette smoking and risk of clinical relapse in patients with crohn's disease. Am J Prev Med 6: 161-166, 1990.
58. Randall DE, **Marshall JR**, Graham S, Brasure J. Patterns in food use and their association with nutrient intakes. Am J Clin Nutr 52: 739-745, 1990.
59. Dowdall GW, **Marshall JR**, Morra WA. Economic antecedents of mental hospitalization: A nineteenth-century time-series test. J Health Soc Behav 31(2): 141-147, 1990.
60. Freudenheim JL, Graham S, Horvath PJ, **Marshall JR**, Haughey BP, Wilkinson G. Risks associated with source of fiber and fiber components in cancer of the colon and rectum. Cancer Res 50: 3295-3300, 1990.
61. Duffy LC, Zielezny MA, **Marshall JR**, Weiser MM, Phillips JF, Byers TE, Calkins BM, Graham S, Ogra PL. Lag time between stress events and risk of recurrent episodes of inflammatory bowel disease. Epidemiology 2: 141-145, 1991.
62. Duffy LC, Zielezny MA, **Marshall JR**, Byers TE, Weiser MM, Phillips JF, Calkins BM, Ogra PL, Graham S. Relevance of major stress events as an indicator of disease activity prevalence in inflammatory bowel disease. Behav Med 17: 101-110, 1991.
63. Randall E, **Marshall JR**, Graham S, Brasure J. High-risk health behaviors associated with various dietary patterns. Nutr Cancer 16(2): 135-151, 1991.
64. Graham S, Hellmann R, **Marshall J**, Freudenheim J, Vena J, Swanson M, Zielezny M, Nemoto T, Stubbe N, Raimondo T. The nutritional epidemiology of postmenopausal breast cancer in Western New York. Am J Epidemiol 134: 552-566, 1991.
65. Randall DE, **Marshall JR**, Brasure J, Graham S. Patterns in food use and compliance with NCI dietary guidelines. Nutr Cancer 15:141-158, 1991.
66. Freudenheim JL, Graham S, **Marshall JR**, Haughey BP, Cholewinski S, Wilkinson G. Folate Intake and carcinogenesis of the colon and rectum. Intl J Epidemiol 20: 368-374, 1991.
67. Duffy LC, Zielezny MA, **Marshall JR**, Weiser MM, Phillips JF, Byers TE, Ogra PL, Graham S. Comparison of stress indices in gauging clinical activity in patients with inflammatory bowel disease. J Traum Stress 5(4): 79-90, 1992.
68. **Marshall JR**, Graham S, Haughey BP, Shedd D, O'Shea R, Brasure J, Wilkinson G, West D. Smoking, alcohol, dentition and diet in the epidemiology of oral cancer. Oral Oncology, Eur J Cancer 28B(1): 9-15, 1992.
69. Lance P, Grossman S, **Marshall JR**. Screening for colorectal cancer. Semin Gastrointest Dis 3: 22-33, 1992.
70. Freudenheim J, Graham S, Byers T, **Marshall J**, Haughey B, Swanson M, Wilkinson G. Diet, smoking and alcohol in cancer of the larynx: A case-control study. Nutr Cancer 17: 33-45, 1992.

71. **Marshall J**, Yinsheng Q, Junshi C, Parpia B, Campbell TC. Additional ecologic evidence: Lipids and breast cancer mortality among women age 55 and over in China. Eur J Cancer 28A(10): 1720-1727, 1992.
72. Bandera EV, Freudenheim JL, Graham S, **Marshall JR**, Haughey BP, Swanson M, Brasure J, Wilkinson G. Alcohol consumption and lung cancer in White males. Cancer Causes Control 3: 361-369, 1992.
73. Randall E, **Marshall JR**, Brasure J, Graham S. Dietary patterns and colon cancer in Western New York. Nutr Cancer 18(3): 265-276, 1992.
74. Vena JE, Graham S, Freudenheim J, **Marshall J**, Zielezny M, Swanson M, Sufrin G. Diet in the epidemiology of bladder cancer in Western New York. Nutr Cancer 18(3): 255-264, 1992.
75. Whittemore AS, Harris R, Itnyre J, Halpern J, and the Collaborative Ovarian Cancer Group (including **Marshall JR**). Characteristics relating to ovarian cancer risk: Collaborative analysis of 12 US case-control studies. I. Methods. Am J Epidemiol 136(10): 1175-1183, 1992.
76. Harris R, Whittemore AS, Itnyre J, Casagrande J, Cramer D, Hartge P, Kelsey J, Lee M, Lee N, Lyon J, **Marshall J**, McGowan L, Nasca P, Paffenbarger R, Rosenberg L, Weiss N, Copley GD. Characteristics relating to ovarian cancer risk: Collaborative analysis of 12 US case-control studies. II. Invasive epithelial ovarian cancer in white women. Am J Epidemiol 136(10): 1184-1203, 1992.
77. Harris R, Whittemore AS, Itnyre J, Casagrande J, Cramer D, Hartge P, Kelsey J, Lee M, Lee N, Lyon J, **Marshall J**, McGowan L, Nasca P, Paffenbarger R, Rosenberg L, Weiss N, Copley GD. Characteristics relating to ovarian cancer risk: Collaborative analysis of 12 US case-control studies. III. Epithelial tumors of low malignant potential in white women. Am J Epidemiol 136(10): 1204-1211, 1992.
78. Whittemore AS, Harris R, Itnyre J, Casagrande J, Cramer D, Hartge P, Kelsey J, Lee M, Lee N, Lyon J, **Marshall J**, McGowan L, Nasca P, Paffenbarger R, Rosenberg L, Weiss N, Copley GD. Characteristics relating to ovarian cancer risk: Collaborative analysis of 12 US case-control studies. IV. The athogenesis of epithelial ovarian cancer. Am J Epidemiol 136(10): 1212-1220, 1992.
79. Graham S, Zielezny M, **Marshall J**, Priore R, Freudenheim J, Brasure J, Haughey B, Nasca P, Zdeb M. Diet in the epidemiology of postmenopausal breast cancer in the New York State cohort. Am J Epidemiol 136(11): 1327-1337, 1992.
80. Vena J, Freudenheim J, Graham S, **Marshall J**, Zielezny M, Swanson M, Sufrin G. Coffee, Cigarette smoking and bladder cancer in Western New York. Ann Epidemiol 3(6): 586-591, 1993.
81. **Marshall J**. Can we really derive etiology from human-based studies? Cancer Res (Suppl.) 53: 2437s-2441s, 1993.
82. Vena JE, Graham S, Freudenheim J, **Marshall J**, Zielezny M, Swanson M, Sufrin G. Drinking water, fluid intake, and bladder cancer in Western New York. Arch Environ Health 48(3): 191-198, 1993.
83. **Marshall JR**, Zielezny MA. Fat and calories in the epidemiology of colon cancer in Western New York. Prev Med 22: 775-782, 1993.
84. Feskanich D, **Marshall J**, Rimm EB, Litin LB, Willett WC. Simulated validation of a brief food frequency questionnaire. Ann Epidemiol 4: 181-187, 1994.

85. Freudenheim JL, **Marshall JR**, Graham S, Laughlin R, Vena JE, Bandera E, Muti P, Swanson M, Nemoto T. Exposure to breastmilk in infancy and the risk of breast cancer. Epidemiology 5: 324-331, 1994.
86. McCann SE, Randall E, **Marshall JR**, Graham S, Zielezny M, Freudenheim JL. Diet diversity and risk of colon cancer in western New York. Nutr Cancer 21: 133-141, 1994.
87. Vena JE, Freudenheim JL, **Marshall JR**, Laughlin R, Swanson M, Graham S. Risk of premenopausal breast cancer and use of electric blankets. Am J Epidemiol 140: 974-979, 1994.
88. Hartge P, Whittemore AS, Itnyre J, McGowan L, Cramer D, The Collaborative Ovarian Cancer Group (including **Marshall JR**). Rates and risks of ovarian cancer in subgroups of white women in the United States. Obstet Gynecol 84: 760-764, 1994
89. Zhang ZF, Vena JE, Zielezny M, Graham S, Haughey BP, Brasure J, **Marshall JR**. Occupational exposure to extreme temperature and risk of testicular cancer. Arch Environ Health 50(1): 13-18, 1995.
90. Zhang ZF, Graham S, Yu SZ, **Marshall J**, Zielezny M, Chen YX, Sun M, Tang SL, Liao CS, Xu JL, Yang XZ. Trichomonas vaginalis and cervical cancer: a prospective study in China. Ann Epidemiol 5: 325-332, 1995.
91. Zhang ZF, Zeng ZS, Sarkis AS, Klimstra DS, Charytonowicz E, Pollack D, Vena J, Guillem J, **Marshall JR**, Cordon-Cardo C, Cohen AM, Begg CB. Family history of cancer, body weight, and p53 nuclear overexpression in Duke's C colorectal cancer. Br J Cancer 71: 888-893, 1995.
92. Macfarlane GJ, Zheng T, **Marshall JR**, Boffetta P, Niu S, Brasure J, Merletti F, Boyle P. Alcohol, tobacco, diet and the risk of oral cancer: a pooled analysis of three case-control studies. Eur J Cancer. Part B, Oral Oncol 31B(3): 181-187, 1995.
93. Freudenheim JL, **Marshall JR**, Graham S, Laughlin R, Vena JE, Swanson M, Ambrosone C, Nemoto T. Lifetime alcohol consumption and risk of breast cancer. Nutr Cancer 23(1): 1-11, 1995.
94. Skelly AH, **Marshall JR**, Haughey BP, Davis PJ, Dunford RG. Self-efficacy and confidence in outcomes as determinants of self-care practices in inner-city, African-American women with non-insulin-dependent diabetes. Diabetes Educator 21(1): 38-46, 1995.
95. Olson SH, Trevisan M, **Marshall JR**, Graham S, Zielezny M, Vena JE, Hellmann R, Freudenheim JL. Body mass index, weight gain, and risk of endometrial cancer. Nutr Cancer 23: 141-149, 1995.
96. Mendola P, **Marshall J**, Graham S, Laughlin RH, Freudenheim JL. Dietary correlates of fat intake. Nutrition and Cancer 23: 161-169, 1995.
97. Xing X, Burr JA, Brasure JR, Neugut AI, **Marshall JR**. Reproducibility of food intake in a food frequency questionnaire used in a general population. Nutrition and Cancer 24(1): 85-95, 1995.
98. Ambrosone CB, Freudenheim JL, Graham S, **Marshall JR**, Vena JE, Brasure JR, Laughlin R, Nemoto T, Michalek AM, Harrington A, Ford TD, Shields PG. Cytochrome P4501A1 and glutathione S-transferase (M1) genetic polymorphisms and postmenopausal breast cancer risk. Cancer Res 55: 3483-3485, 1995.
99. Ambrosone CB, **Marshall JR**, Vena JE, Laughlin R, Graham S, Nemoto T, Freudenheim JL. Interaction of family history of breast cancer and dietary antioxidants with breast cancer risk (New York, United States). Cancer Causes and Control 6: 407-415, 1995.

100. **Marshall JR**. Improving Americans' diet – setting public policy with limited knowledge. Am J Public Health 85(12): 1609-1611, 1995.
101. Ambrosone CB, Freudenheim JL, **Marshall JR**, Graham S, Vena JE, Brasure JR, Michalek AM, Laughlin R, Nemoto T, Shields PG. The association of polymorphic N-Acetyltransferase (NAT2) with breast cancer risk. Ann NY Acad Sci 768: 250-252, 1995.
102. Boyle P, Maisonneuve P, Andreoni B, **Marshall JR**, Scully C. Prevention of upper gastrointestinal tract cancer: Recent advances in the treatment and biology of solid tumours. Proc Med Publ Found 27-33, 1995.
103. Freudenheim JL, **Marshall JR**, Vena JE, Laughlin R, Brasure JR, Swanson MK, Nemoto T, Graham S. Premenopausal breast cancer risk and intake of vegetables, fruits, and related nutrients. J Natl Cancer Inst 88(6): 340-348, 1996.
104. **Marshall JR**, Hastrup JL. Mismeasurement and the resonance of strong confounders: uncorrelated errors. Am J Epidemiol 143(10): 1069-1078, 1996.
105. Marshall JR, Boyle P. Nutrition and oral cancer. Cancer Causes Control 7: 101-111, 1996.
106. Zhang ZF, Zhang ZZ, Yu SZ, **Marshall JR**, Zielezny MA, Graham S, Chen YX, Yang XZ. Geographical distribution of risk factors and incidence of cervical cancer in Southeast China. J Epidemiology and Community Health 50: 104-105, 1996.
107. Xing X, Burr JA, Brasure JR, Neugut AI, **Marshall JR**. Reproducibility of food intake in a food frequency questionnaire used in a general population. Nutr Cancer 25: 259-268, 1996.
108. Hunter DJ, Spiegelman D, Adami HO, Beeson L, van den Brandt PA, Folsom AR, Fraser GE, Goldbohm RA, Graham S, Howe GR, Kushi LH, **Marshall JR**, McDermott A, Miller AB, Speizer FE, Wolk A, Yaun S, Willett W. Cohort studies of fat intake and risk of breast cancer – a pooled analysis. N Engl J Med 334(6): 356-361, 1996.
109. Freedman AN, Michalek AM, **Marshall JR**, Mettlin CJ, Petrelli NJ, Zhang ZF, Black JD, Satchidanand S, Asirwatham JE. The relationship between smoking exposure and p53 overexpression in colorectal cancer. Br J Cancer 73(8): 902-908, 1996.
110. Shields PG, Ambrosone CB, Graham S, Bowman ED, Harrington AM, Gillenwater KA, **Marshall JR**, Vena JE, Laughlin R, Nemoto T, Freudenheim JL. A cytochrome P4502E1 genetic polymorphism and tobacco smoking in breast cancer. Mol Carcinog 17: 144-150, 1996.
111. Ambrosone CB, Freudenheim JL, Graham S, **Marshall JR**, Vena JE, Brasure JR, Michalek AM, Laughlin R, Nemoto T, Gillenwater KA, Harrington AM, Shields PG. Cigarette smoking, N-acetyltransferase 2 genetic polymorphisms, and breast cancer risk. J Am Med Assoc 276: 1494-1501, 1996.
112. Ambrosone CB, Kato S, Bowman ED, Harrington AM, Blomeke B, Freudenheim JL, Graham S, **Marshall JR**, Vena JE, Brasure JR, Shields PG. Molecular epidemiology of lung and breast cancer. Eur J Cancer Prev 5(5): 391-392, 1996
113. Ip C, **Marshall JR**. Trans fatty acids and cancer. Nutr Rev 54: 138-145, 1996.
114. Gruber M, **Marshall JR**, Zielezny M, Lance P. A case-control study to examine the influence of maternal perinatal behaviors on the incidence of Crohn's disease. Gastroenterol Nurs 19: 53-9, 1996.
115. Violanti JM, **Marshall JR**. Cellular phones and traffic accidents: An epidemiological approach. Accid Anal Prev 28: 265-70, 1996.
117. Violanti JM, Vena JE, **Marshall JR**. Suicides, homicides, and accidental death: a comparative risk assessment of police officers and municipal workers. Am J Ind Med 30(1): 99-104, 1996.

118. Violanti JM, Vena JE, **Marshall JR**, Petralia S. A comparative evaluation of police suicide rate validity. Suicide Life Threat Behav 26(1):79-85, 1996.
119. Freedman AN, Michalek AM, **Marshall JR**, Mettlin CJ, Petrelli N, Black JD, Zhang ZF, Satchidanand S, Asirwatham JE. Familial and nutritional risk factors for p53 overexpression in colorectal cancer. Cancer Epidemiol Biomarkers Prev 5(4): 285-291, 1996.
120. Schatzkin A, Lanza E, Freedman LS, Tangrea J, Cooper MR, **Marshall JR**, Murphy PA, Selby JV, Shike M, Schade RR, Burt RW, Kikendall W, Cahill J. The polyp prevention trial I: Rationale, design, recruitment, and baseline participant characteristics. Cancer Epidemiol Biomarkers Prev 5: 375-383, 1996.
121. **Marshall JR**, Fay D, Lance P. Potential costs of flexible sigmoidoscopy-based colorectal cancer screening. Gastroentrology 111(6): 1411-1417, 1996.
122. Hunter DJ, Spiegelman D, Adami HO, van den Brandt PA, Folsom AR, Goldbohm RA, Graham S, Howe GR, Kushi LH, **Marshall JR**, Miller AB, Speizer FE, Willett W, Wolk A, Yaun SS. Non-dietary factors as risk factors for breast cancer, and as effect modifiers of the association of fat intake and risk of breast cancer. Cancer Causes Control 8: 49-56, 1997.
123. **Marshall JR**, Lanza E, Bloch A, Caan B, Caggiula A, Quandt S, Iber F, Kikendall W, Slattery M, Sowell A. Indexes of food and nutrient intakes as predictors of serum concentrations of nutrients: The problem of inadequate discriminant validity. Am J Clin Nutr 65(suppl): 1269S-1274S, 1997.
124. **Marshall JR**, Alberts D, Sampliner R. Colon cancer reduction. Questions about implementation of proven techniques (Editorial). Arch Intern Med 157(17): 1919-1920, 1997.
125. Bandera EV, Freudenheim JL, **Marshall JR**, Zielezny M, Priore RL, Brasure J, Baptiste M, Graham S. Diet and alcohol consumption and lung cancer risk in the New York State Cohort (United States). Cancer Causes Control 8: 828-840, 1997.
126. Freudenheim JL, **Marshall JR**, Vena JE, Moysich KB, Muti P, Laughlin R, Nemoto T, Graham S. Lactation history and breast cancer risk. Am J Epidemiol 146(11): 932-938, 1997.
127. Russell M, **Marshall JR**, Trevisan M, Freudenheim JL, Chan AWK, Markovic N, Vana JE, Priore RL. Test-retest reliability of the cognitive lifetime drinking history. Am J Epidemiol 146(11): 975-981, 1997.
128. Zhang ZF, Kurtz RC, **Marshall JR**. Cigarette smoking and adenocarcinomas of esophagus and gastric cardia [Editorial]. J Natl Cancer Inst 89(17): 1247-1249, 1997.
129. Olson SA, Vena JE, Dorn JP, **Marshall JR**, Zielezny M, Laughlin R, Graham S. Exercise, occupational activity, and risk of endometrial cancer.Ann Epidemiol 7(1): 46-53, 1997.
129. Smith-Warner SA, Spiegelman D, Yaun S-S, van den Brandt PA, Folsom AR, Goldbohm A, Graham S, Holmberg L, Howe GR, **Marshall JR**, Miller AB, Potter JD, Speizer FE, Willett WC, Wolk A, Hunter DJ. Alcohol and breast cancer in women: A pooled analysis of cohort studies. J Am Med Assoc 279(7): 535-540, 1998.
130. Moysich MB, Ambrosone CB, Vena JE, Shields PG, Meldola P, Kostyniak P, Greizerstein H, Graham S, **Marshall JR**, Schisterman EF, Freudenheim JL. Environmental organochlorine exposure and postmenopausal breast cancer risk. Cancer Epidemiol Biomarkers Prev 7: 181-188, 1998.

131. Thompson PA, Shields PG, Freudenheim JL, Stone A, Vena JE, **Marshall JR**, Graham S, Laughlin R, Nemoto T, Kadlubar FF, Ambrosone CB. Genetic polymorphisms in Catechol-*O*-Methyltransferase, menopausal status, and breast cancer risk. Cancer Res 58: 2107-2110, 1998.
132. Martinez ME, **Marshall JR**, Sechrest L. Invited commentary: Factor analysis and the search for objectivity. Am J Epidemiol 148(1): 17-19, 1998.
133. Martinez ME, Reid ME, Guillen-Rodriguez J, **Marshall JR**, Sampliner R, Aickin M, Ritenbaugh C, van Leeuwen B, Mason-Liddil N, Giuliano A, Vargas PA, Alberts DS. Design and baseline characteristics of study participants in the wheat bran fiber trial. Cancer Epidemiol Biomarkers Prev 7: 813-816, 1998.
134. Mendola P, Moysich KB, Freudenheim JL, Shields PG, Schisterman EF, Graham S, Vena JE, **Marshall JR**, Ambrosone CB. Risk of recurrent spontaneous abortion, cigarette smoking and genetic polymorphisms in NAT2 and GSTM1. Epidemiology 9(6): 666-668, 1998.
135. Freedman An, Michalek AM, Weiss HA, Zhang ZF, **Marshall JR**, Mettlin CJ, Asirwatham JE, Petrelli NJ, Caporaso NE. Aspirin use and p53 expression in colorectal cancer. Cancer Detect Prev 22(3): 213-218, 1998.
136. Moysich KB, Shields PG, Freudenheim JL, Schisterman EF, Vena JE, Kostyniak P, Greizerstein H, **Marshall JR**, Graham S, Ambrosone CB. Polychlorinated bephenyls, cytochrome P4501A1 polymorphism, and postmenopausal breast cancer risk. Cancer Epidemiol Biomarkers Prev 8: 41-44, 1999.
137. Ambrosone CB, Freudenheim JL, Thompson PA, Bowman E, Vena JE, **Marshall JR**, Graham S, Laughlin R, Nemoto T, Shields PG. Manganese Superoxide Dismutase (*MnSOD*) genetic polymorphisms, dietary antioxidants, and risk of breast cancer. Cancer Res 59: 602-606, 1999.
138. Earnest DL, Sampliner RE, Roe DJ, van Leeuwen B, Guillen J, Reid M, Martinez ME, **Marshall JR**, Alberts DS. Progress report: The Arizona Phase III study of the effect of wheat bran fiber on recurrence of adenomatous colon polyps. Am J Med 106(1A): 43S-51S, 1999.
139. Martinez ME, Marshall JR, Alberts DS. Dietary fiber, carbohydrates, and cancer. Nutritional Oncology. Academic Press, 185-194, 1999.
140. **Marshall JR**, Chen Z. Diet and health risk: Risk patterns and disease-specific. Am J Clin Nutr 69(6): 1351S-1356S, 1999.
141. **Marshall JR**, Hastrup JL, Ross JS. Mismeasurement and the resonance of strong confounders: Correlated errors. Am J Epidemiol 150(1): 88-96, 1999.
142. McCann S, **Marshall JR**, Russell M, Markovic N. Recent alcohol intake as estimated by the Health Habits and History Food Frequency Questionnaire, the Harvard Semiquantitative Food Frequency Questionnaire and a more detailed alcohol intake questionnaire. Am J Epidemiol 150(4): 334-340, 1999.
143. Zhang ZF, Kurtz RC, Klimstra DS, Yu GP, Sun M, Harlap S, **Marshall JR**. Helicobacter pylori infection on the risk of stomach cancer and chronic atrophic gastritis. Cancer Detect Prev 23(5): 357-367, 1999.
144. **Marshall JR**, Martinez ME, Alberts DS. Wheat bran as a means of cancer chemoprevention. Asia Pacific J Clin Nutr 8(Suppl): S47-S53, 1999.

145. The WISEWOMAN Workgroup (including **Marshall JR**). Cardiovascular disease prevention for women attending breast and cervical cancer screening programs: The WISEWOMAN Projects. Preventive Medicine (in press, 1999).
146. van den Brandt PA, Spiegelman D, Yaun S-S, Adami H-O, Beeson L, Folsom AR, Fraser G, Goldbohm RA, Graham S, Kush L, **Marshall JR**, Miller AB, Rohan T, Smith-warner SA, Speizer FE, Willett WC, Solk A, Hunter DJ. A pooled analysis of prospective cohort studies on height, weight and breast cancer risk. Am J Epidemiol (in press, 1999).
147. Montironi R, Mazzucchelli R, **Marshall JR**, Bartels PH. Prostate cancer prevention. Review of target populations, pathological biomarkers, and chemopreventive agents. J Clin Pathol (in press, 1999).
148. Cancer Detect Prev (in press, 1999).
149. **Marshall JR**. Diet and breast cancer survival: An abundance of hope, a dearth of evidence. Editorial. Cancer (in press, 1999).
150. Martinez ME, Maltzman T, **Marshall JR**, Einspahr J, Reid ME, Sampliner R, Ahnen DJ, Hamilton SR, Alberts DS. Risk factors for ki-ras protoncogene motation in sporadic colorectal adenomas. Cancer Research (in press, 1999).
151. Martinez, M. D., Marshall, J. R., Graver, E., Whitacre, R. C., Woolf, K., Ritenbaugh, C., and Alberts, D. S. Reliability and validity of a self-administered food frequency questionnaire in a chemopreventive trial of adenoma recurrence. Cancer Epidemiol Biomarkers & Prev (in press, 1999).